LEVEL 1 - 11 OF 18 STORIES

June 18, 1997, Wednesday

HEADLINE: The Advisory Committee on Tobacco Policy and Public Health

LOCATION: Radisson Barcelo Hotel 2121 P Street, NW Washington, D.C.

TIME: 8:37 a.m.

NAME: Dr. Kessler & Dr. Koop, Chairmen

LENGTH: 55991 words

P R O C E E D I N G S

(8:37 a.m.)

DR. KOOP: Good morning, ladies and gentlemen. Could we please come to order.

And welcome to the second meeting of the Advisory Committee on Tobacco Policy and Public Health.

I'm glad you all could be here and I know that a lot of you have been doing yeoman's work on reports between the last time we met and now.

We are here today to receive reports from several subcommittees that were tasked with specific assignments when last we met on June 5th. We will do that, and we will do it first.

And then, before we discuss those reports, we will have several presentations, some from those whose organizations are on this Committee, and at least one from the world of law.

We are doing this because I think we deserve the same openness and courtesy paid us, as has been afforded the press and, through them, the public.

I know it is difficult at times for us to separate our task of providing a blueprint on tobacco control to the Congress from the more contentious and perhaps more glamorous endeavor, which we referred to last time as the "Tobacco Talks," but now seem to be known as the Settlement Talks.

Let me remind you once again of our charge. We were asked to draw up a blueprint for guidelines for a template for a tobacco control policy that could inform the Congress and, if the occasion arose, be used as a standard by which to judge the settlement if one is forthcoming.

Separately, long before we were asked to act as an Advisory Committee to Congress, there were secret talks underway which, when they became known to the public, prompted some members of Congress to establish this Committee.

These meetings, which I am now calling the Settlement Talks have been a series of dialogues among a limited collection of players in the tobacco wars, where public health interests have been fully represented, not qualitatively but quantitatively.

Now, although I am at time unhappy about the manner in which the Settlement Talks have been carried out, as I am at times about the tendency of some members of this Committee to vie with each other for press coverage, I want you to know that I understand that such activity is borne of frustration, and that I am quite empathic to that.

I am also convinced that before we proceed with a discussion of our blueprint for tobacco control, we should hear from some of those who have been privileged to be part of the Settlement Talks.

The progress that they have made or are likely to make in the future should be part of our knowledge before we discuss the several subcommittee reports.

So we will proceed to the reports, ad seriatim, with holding questions until the end because there may be some overlap in these subcommittee reports.

If they get too long-winded, Dr. Kessler may choose to alter that form somewhat.

Let me say a few things about housekeeping. You all have in front of you some reports, as well as a transcript of June 5th's meeting. In order for that transcript to be accurate, you must talk directly into the microphones.

You will note that there are two microphones today. The second one is held on in a rather precarious manner, and so we have been asked by the sound people to handle these microphones gingerly as you pass them from one to the other.

And now Dr. Kessler, who was here for the entire meeting last time, when I had to leave, and who knows more about the subcommittee setups is going to take over the chairmanship.

DR. KESSLER: Thank you, Dr. Koop.

Let's just start with our overall goal, which is to reach a consensus on the public health principals, that should guide a national tobacco policy.

Let me just ask and make sure that, as you left this last meeting, that we are all still in agreement that that is our goal.
I see some heads nodding.

Let's move on. I think that's helpful and important to keep that goal in mind. I am confident, I am very confident and hopeful that we will, in fact, reach a consensus on public health principles.

As Dr. Koop said, there are five subcommittees, and we will start with them.

Let me first ask if anyone has anything for the record that they would like to submit.

DR. BANZHAF: Mr. Chairman, John Banzhaf of Action on Smoking and Health.

Antismoking colleagues from around the world, more specifically from 19 different countries, have sent us and the people engaged in the settlement talks a resolution regarding the worldwide implications of it.

I would like to read only two sentences.

They say it is unacceptable to discuss a comprehensive settlement of the U.S. tobacco litigation which does not include measures to control the use of U.S. tobacco products outside the United States.

To avoid doing public health harm, a settlement must set a worldwide floor on U.S. tobacco company practices without limiting the ability of countries to require companies to exceed the global minimum standard.

Since this comes to us from people who are worldwide leaders in the war on smoking, people whose names, I think, most of us would recognize, like Judith McKai (ph), recently featured on 60 Minutes; Dr. Nigel Gray, my colleague; Professor Simon Chapman from Australia.

I would like to submit that statement for the record. Copies have been given to every member of the Committee, and I hope that at some appropriate point, presumably not today, this Committee will consider it, as will the various subcommittees.

Thank you for the opportunity.

DR. KOOP: Thank you.

DR. KESSLER: Any other issues for the record?

(No response.)

SUBCOMMITTEE REPORTS

DR. KESSLER: Let us move to the first Subcommittee, the Youth Committee,

which had 11 members formally on it.

Dr. Heyman, will you be kind enough to start? I think we will ask as general instructions, five to ten minutes, erring on the shorter side.

What we will do is we are going to have this afternoon for discussion, but within limits; two, three, four questions of clarification after each panel, not for debate. Nothing other than questions of clarification after this so we can proceed rather expeditiously, but thank you, Dr. Heyman.

Why don't you start. Are you comfortable there, or would you like to sit --

DR. HEYMAN: It's your pleasure, Dr. Kessler.

DR. KESSLER: Maybe if you move to the center, and this way you can see everybody and not in a corner.

SUBCOMMITTEE ON YOUTH AND TOBACCO

DR. HEYMAN: Good morning. My name is Richard Heyman -- H-e-y-m-a-n. I'm the Chairman of the Committee on Substance Abuse for the American Academy of Pediatrics and am, in fact, sitting in for Dr. George Comerci, who was with this group last time.

I've had the privilege of working on the tobacco issue for a number of years now, on behalf of the American Academy of Pediatrics, and bring to you today a preliminary report of the Task Force on Youth and Tobacco.

Our group met this morning, at 7:30 this morning, to try to review a rather lengthy document which has been pulled together over the last six or seven days, and we will have that document to submit to this group within the next half hour, as soon as the ink dries.

The most important provisions that come out of our recommendations are the following:

We submit to this group that the most important consideration as a national tobacco policy is drafted is the fact that 90 percent of young people, 90 percent of people who use tobacco on a regular basis, in fact, begin to do so before the age of 19.

And, thus, the initiation of tobacco is, in fact, a pediatric problem, as you so eloquently described in the FDA Rule which was developed last year, and therefore it has to be the thrust of any national tobacco program; namely, to discourage and inhibit the access and use of tobacco by youth.

There are a variety of reasons why young people begin to use tobacco, but the most important factor to recognize is the fact that over the years this product has been conveyed to young people as being a normal product for young people to use.

It has been conveyed as conveying the ability to be macho and independent and tough and sexy and thin, and the incredibly effective role that the tobacco industry has played in getting young people to use this addicting product, is

the reason why we have the problem in our country today.

Our task force calls for a number of provisions. Many of them build upon the FDA Rule, and we take the FDA Rule as the cornerstone and a sine qua non of any tobacco settlement.

The FDA regulations must be put in place and must be enforced and, furthermore, we call for a complete ban on the promotion and the advertising of tobacco products in all venues and in all media.

We call for the prohibition of the tobacco industry in terms of the promotion of its products through the sponsorship of events, whether these be athletic or cultural or social events.

We call for a complete and absolute ban on all tobacco logo apparel; on the distribution and availability of any kind of devices or services that, in fact, carry a tobacco emblem or logogriph.

We call upon the people who work out this settlement to work out a very elaborate program of public education, which would feature counter-advertising and effective counter-advertising, advertising which would have the net effect of developing a decrease in youth use.

Furthermore, we call for specific outcome measures to be developed, and specifically we look for the industry to participate actively in this program to decrease youth tobacco use and, in fact, to be subject to penalties if youth tobacco use fails to drop by 30 percent in five years, 50 percent in 7 years, and 60 percent in 10 years.

These very specific outcome measures must be met because we know that the tobacco industry needs young smokers in order to replace those who quit and those who die, and we also know that the tobacco industry and the advertising industry have been incredibly effective over the years in getting young people to take up the habit.

We call for the FDA to enforce its regulation of nicotine as a drug, and for the FDA to continue its efforts to develop appropriate warnings on packaging, such warnings to be revised in terms of the place on the package and the wording that is used.

We look for a very elaborate enforcement mechanism that would monitor the sale of tobacco to young people, so that in fact young people truly can't buy tobacco under the age of 18. We want tobacco placed in places where it can't be purchased.

We want the counter displays to be eliminated, and we call upon a very elaborate program of enforcement, including so-called sting operations, to monitor the effectiveness of the program.

We look for the funding of general education programs, both in the community and in the schools and, again, we look for the industry, as well as excise taxes, to fund that.

We call for a significant and major increase in the tobacco excise tax and a

complete end to subsidies to the tobacco industry so that the price of the tobacco product, in fact, is prohibitive for young people.

We know through research done in a number of states that, in fact, young people are very sensitive to the price of the tobacco products and we feel that this is yet another very effective way to discourage youth initiation.

In summary, we would like to submit to this group that the whole issue of tobacco control policy, in fact, involves around getting young people to make the decision not to smoke.

While the decision not to use tobacco products for our young people is a multifactorial decision, we feel very strongly that the advertising, promotion, access, and price issues are extremely important in that area.

Thank you, Dr. Kessler.

DR. KESSLER: Thank you very much for a very clear and concise presentation.

QUESTIONS AND ANSWERS

DR. KESSLER: Let's take a few questions of clarification or elucidation.

May I ask two questions to start?

The penalties. Was there any discussion of what it would take for penalties/incentives to achieve those goals by your subcommittee?

DR. HEYMAN: We looked at several issues, Dr. Kessler.

Number one, we looked at financial penalties and batted around several different numbers. And I would like the opportunity to look at a few more statistics before sharing those with you.

One very important penalty, which we would like to propose and will be including in our detailed report, is the concept of plain packaging, so that if, in fact, the tobacco industry did not meet its market of 30 percent drop in five years -- 50 and 7 and 60 -- in ten years, we would enforce the plain packaging rule on them.

That would be one of the penalties that they would inure to them if these targets were not met.

DR. KESSLER: You used the phrase "prohibitive" as with regard to the price of cigarettes; prohibitive for young people to buy, in reality.

Do you have any sense of what that would be in current market terms?

DR. HEYMAN: Again, I'd like to defer on that because we're going to look at information from several California studies and come up with a specific figure there. But we do know, as the price rises, that the consumption by young people, particularly, drops. So we will have that data available to incorporate into our final report.

DR. KESSLER: Why don't we just go around quickly and ask for other questions of clarification. Let me start at this end and then we can just go ahead and ask questions of clarification. Again, two or three.

DR. VEAL: I served on the Committee, and I have no question, actually, but a point of emphasis; and that is, that we feel there needs to be a strong program of research, which involves adolescent and maternal tobacco use, cessation interventions.

We feel that, for youth, those who start treatment is especially important.

DR. KESSLER: That's a very important point.

Other members of your subcommittee, we'll start with them; I apologize. Would they like to add or clarify anything that's been said?

(No response.)

DR. KESSLER: Bob, do you have a question?

DR. GRAHAM: Dr. Heyman, a significant amount of emphasis on your recommendations is not allowing individuals to begin smoking before the age of 18.

Were we to be successful in that goal, do we have any insight from other countries about the likely behavior is of initiating use of tobacco products after the age of 18, which is not one of the areas that you targeted.

DR. HEYMAN: The statistics show very clearly that the likelihood of initiating tobacco use after the age of 19, and this appears to be on a global basis, is, in fact, very low.

Because most of the time, by the time young people have reached the age of 19, they've gone through some of this development of so-called "formal operational thinking," which allows them to recognize the consequences of their actions.

Also, they become much less subjective to peer pressure and to the role of the media and to advertising and promotion, so that the whole -- the major reason why our young Americans begin to smoke, and in fact evidence suggests that this is a worldwide phenomenon, is based on the issues that we outlined already.

DR. KESSLER: Anyone else on this side of the table have a question of Dr. Heyman?

Ms. Carol.

MS. CAROL: In my experience with youth, they are very much swayed by issues of secondhand smoke. Not only do they not want to breathe it themselves but once they start understanding that people don't want to be around smoke, it's a smoking prevention strategy.

How did you deal with secondhand smoke in your report?

DR. HEYMAN: On the issue of environmental tobacco smoke, I believe, is covered by one of Dr. Kessler's other task forces, so our committee did not discuss that issue, specifically.

DR. KESSLER: Let's move to this side of the table.

Ms. McGrath.

MS. McGRATH: Thank you. I have a question with regard to counter-advertising campaigns.

Did your committee consider the gender and ethnic differences that need to be targeted to be effective in reaching different groups of youth?

DR. HEYMAN: Yes, ma'am, we did. And that's one of the provisions in our formal statements, which you will receive a copy of today, that these counter-advertising campaigns must be locally sensitive, community-sensitive, culturally sensitive, ethnically diverse, and appropriate for the age to which they're aimed. Very important; and gender appropriate as well.

MS. McGRATH: Thank you.

DR. BANZHAF: Doctor, did your committee consider the problem of the dramatic increase in smoking in movies over the past number of years in the preliminary investigation now being conducted by the Justice Department into the possibility that that's caused by payments by the tobacco industry?

If so, what are your recommendations? If not, why did you not consider it?

DR. HEYMAN: We did consider that, and there is a statement in our final statement, which states that we would recommend the prohibition of the payment of fees or in-kind services in exchange for placement or use of tobacco products in movies or television.

There is a further statement that would prohibit the placement of them, so not only the placement but the payment of fees for the placement.

So we had a detailed discussion about that as well.

DR. KESSLER: Further around this table.

REV. BROWN: There are two questions I want to ask or get clarification on.

One, you used the word "elaborate" several times. Is that meaning well funded or large or big?

(Laughter)

DR. HEYMAN: It means nebulous enough to allow us to think further on the issue.

(Laughter)

REV. BROWN: And, secondly, are issues around Native Americans, tobacco use on the reservation by young people, is that, in fact, taken into account,

particularly the special relationship that sovereign nations have in this process and that they don't necessarily come under all of the federal laws that we have?

Is that taken into account or a special section recognizing what that might look like?

DR. HEYMAN: We have asserted the right of states to manage this issue; asserted the rights of community-based organizations to set standards and policies.

And while we did not specifically mention Native Americans under the provisions, I feel that they would be subsumed under that paragraph, but I will jot that down and make a careful note as we review this.

DR. KESSLER: I think I skipped over Dr. Fielding.

DR. FIELDING: Yes. I was a member of that, am a member of that Committee.

One of the issues that is very important is the role of the media, and it's not only a question of product placement, it's really the question of who in the media, who on TV and who in the movies is smoking.

While it's not an issue of regulatory issue, it is a very important and perhaps essential opportunity for partnership with the TV and the movie industry that we are recommending as part of this Committee report.

DR. KESSLER: This afternoon we'll ask you to come back to that table and we can have broader discussion on each of these subcommittees.

The goal, again, today is to make sure that we have put on the table all of the issues so that the Subcommittee can go back and then consider all of the issues. That's the goal for today in each of these areas.

Dr. Wasserman, and then we'll move on to the next subcommittee.

DR. WASSERMAN: I was just thinking, if I were the tobacco industry and I was looking at this committee and I was looking at my history with children, and all of the standards age 18 and under, I would agree to that, and then I would put in a massive advertising campaign, no hold barred, on college use.

So I think this committee ought to look at what we can do to protect college youth, which would be the next youth market to go after.

DR. KESSLER: Dr. Wasserman, why don't we let you have the first question for discussion, that point, this afternoon. We can start with that issue.

Dr. Heyman, again, much thanks.

CURRENT SMOKERS

The second subcommittee is Current Smokers. There were eight members of that subcommittee.

Dr. Houston, thank you very much. Tom Houston.

Let me just ask and make sure, is everyone comfortable with this format of proceeding? I'm trying to keep it moving, but I don't want to cut anyone off. Is everyone comfortable?

Okay. Dr. Houston.

DR. HOUSTON: Good morning. I'm Tom Houston. I'm Director of the Department of Preventive Medicine at the American Medical Association, and I'm representing Dr. Randolph Smoak at this meeting today. He was detained at a Board meeting.

Our subcommittee -- again, and my thanks to all of them -- came together with a variety of points that I will outline briefly and then entertain questions.

First of all, we recognize that smoking cessation guidelines for clinicians and health care providers have been done. The agency for health care policy and research have a superb document that has been written recently, and we don't need to reinvent the wheel.

However, smoking cessation programs must be featured as a comprehensive part of tobacco of use, prevention and control, and a clear focus on treatment of those who use tobacco have to be included in what we do and should become a cornerstone of clinical practice.

Better access to cessation programs for the program generally, and to information on the availability of those programs is one of the important points to be taken into account.

Enhanced intervention systems for smokers would include health plan coverage, universal health plan coverage for cessation and improved therapy using all of th techniques that are available currently and that might be made available through research in the future.

That would include reimbursement, for example, through federal, private, HMO, and other systems that deal not only with group counseling and the kinds of therapy that people think about traditionally in substance abuse, but individual counseling with all levels of clinicians who should be providing that; and,

Reimbursement for or payment for nicotine replacement therapy and other forms of pharmacotherapy that might be shown to be useful.

Education and public awareness programs for persons who smoke are essential as well.

Although primary prevention by keeping people from starting is the key. Current smokers must be informed, using the most powerful methods available as to the need to stop.

And, again, to the availability and desirability of their entering into smoking cessation programs or working individually with their health care providers.

Behavior change is the goal, and public demand is one of the keys in the effort to drive change.

Redesigned and strongly-directed smoking cessation education is very important for medical students and other clinicians.

One of the things that our committee strongly suggests is that this become an integral part of curricula at all levels of medical training, medical nursing, nurse practitioner, and other health care training;
And as a part of lifelong learning and continuing medical education for practicing health care provisions.

Public awareness programs must be directed at specific populations and subgroups, such as persons of color, women, youth, those with special occupational hazards, Native Americans, and soon.

Research is essential to solving the personal health medical care and public health problems caused by tobacco use, and under this area we regard epidemiologic information and continued surveillance as extremely important;

Sustained high levels of research funding on tobacco use therapeutics and cessation program outcomes, so that we know what works and can refine what it is that we do in clinical practice.

And specific research on cessation for youth and populations that our epidemiology identifies as problems. Pregnant women, for example, and perhaps other subgroups that can be identified in the future.

Finally, the environment needs to be addressed in this issue, so that the public believes tobacco use to be a treatable condition and that the expectation is that people should enter smoking cessation programs or seek care from their health care providers.

It should be acceptable and easy to seek help.

It should be made very clear to the public that this is not a matter of sin or guilt or lack of willpower, but that the proper framework about tobacco use be included in education, broadly speaking; and,

Other environmental issues that other groups around the table will address should be reemphasized, such as increased pricing of tobacco products, restrictions on environmental tobacco smoke, and bans on advertising and promotion, all of which serve to reinforce the smoking cessation message, should be put in place.

QUESTIONS AND ANSWERS

DR. KOOP: In as much as this is a blueprint to advise Congress, did you undertake any kind of discussion about indigent people who would not be able to be covered by health plans and whether that is an obligation of government, in view of the fact that we have about 50 million nicotine addicts out there right now?

DR. HOUSTON: Inasmuch as we said that health care coverage for smoking cessation should be universally available under whatever plans -- federal, state, and so on -- yes, we did.

We recognize that there are persons who don't have insurance and don't have access to that, but that's beyond the scope, I think, of this particular committee.

DR. KESSLER: Why don't we start at Dr. Wasserman's end of the table. Again -- oh, I apologize. I skipped over other members of the subcommittee; points of clarification? Things you would like to add, things that were skipped over in this presentation?

(No response.)

DR. KESSLER: Why don't we start at Dr. Wasserman's end and ask whether there are any questions for clarification.

Anything at that end of the table? No.

John?

DR. BANZHAF: Yes. Did your subcommittee consider the recommendation of the National Association of Insurance Commissioners in 1986, that health insurance plans, particularly HMOs, required differential rates; that is, higher rates for smokers than for nonsmokers, particularly if you're going to be including smoking and all expenses in this, as one of the ways of providing a strong incentive for them to quit?

DR. HOUSTON: No, we didn't look at those specific areas. That's a good recommendation, and you could burden that to life insurance policies and other things, but we did not look at that specifically.

DR. KESSLER: Anyone else?

Jeff?

MR. NESBIT: I have a question of Dr. Houston.

In looking at the cost of care, did your committee consider acquiring the smoking cessation costs incurred, both public and private, be reimbursed by the tobacco companies? Putting it bluntly, they got people addicted, perhaps they should get them unaddicted.

DR. HOUSTON: We didn't consider that as a method of financing, although that certainly is an attractive option.

Under the settlement discussions, as some of the members of the committee understand it, that's one of the potential options, as well as surveillance and monitoring for current smokers and working with persons who are at high-risk for developing tobacco-related diseases, in monitoring their condition and figuring out ways to particularly focus on persons who are heavily addicted and can't stop, and so no.

But, no, we didn't look at the industry financing as a specific mechanism.

DR. KESSLER: We would ask you to consider all of these comments, as well as

the comments this afternoon, and your staff can be making note of these so you can consider, if you think it's appropriate for inclusion.

DR. KOOP: I think, however, Tom, you are drawing the proper line. As I keep trying to remind us, we are not the Settlement Committee. And, as far as we are concerned, we are telling Congress what an ideal tobacco control policy might be.

So it might contain things that, if a settlement were made, and if they were offered something, they could measure it against that.

DR. HOUSTON: Correct. That was the approach we took. Yes.

DR. KESSLER: John's end of the table.

On this leg?

(No response.)

DR. KESSLER: Terrific. Thanks, Tom.

Mr. Garrison, Environmental Tobacco Committee report.

ENVIRONMENTAL TOBACCO COMMITTEE

MR. GARRISON: Thank you, Dr. Kessler, Dr. Koop.

I would first refer your attention, before I make my comments, of the introduction to the report, which has been passed out to you.

That introduction, which we're all familiar with, points out the very adverse consequences of environmental tobacco smoke, and I don't intend to go over those, the number of deaths, et cetera, but I would commend that to your attention, and I will get right into our recommendations.

The Committee believes that all Americans are entitled to a smoke-free environment.

The Committee recommends that federal, state, local legislation, and regulations be enacted to protect all Americans from the physical irritation, disease, disability, and death attributable to ETS.

Accomplishing this goal will also require renewed education efforts to increase the public awareness of the health effects of exposure of environmental tobacco smoke.

To accomplish these goals, the Committee recommends the following:

(1) All jurisdictions enact and enforce legislation and regulations to eliminate exposure to environmental tobacco smoke by prohibiting smoking.

Policy actions include, but are not limited to actions listed below. These are not necessarily in order of priority:

That Congress should enact legislation to the full extent of its jurisdiction

and prohibit smoking in all worksites and in all places of public assembly;

Such action must not preempt or otherwise limit or preclude state and local jurisdictions from acting similarly.

Further, Congress should enact regulations to protect all of its employees from exposure to environmental tobacco smoke by prohibiting smoking from all worksites and places of public assembly directly within its jurisdiction.

State and local governments should enact legislation regulation and ordinance requiring prohibition of smoking in all worksites.

Such regulation should also include requirements for public awareness campaigns related to the health effects of exposure from environmental tobacco smoke.

State governments should establish comprehensive, clean, indoor air legislation that prohibits smoking from all public places -- and this is important -- including outdoor areas where people assemble and congregate without preemption of local mandates.

Such regulations should also include requirements for public awareness campaigns related to the health effects of exposure to environmental tobacco smoke.

State and local school boards should enact regulations requiring all elementary and secondary schools to be 100 percent smoke free in all areas of the campus.

State and local school boards should revise comprehensive school-health education programs and general health education programs to include subject matter on the health effects of exposure from environmental tobacco smoke.

Congress should enact legislation to the full extent of its jurisdiction to implement the International Civil Aviation Organization resolution by requiring all international airline flights originating from or landing in the United States or its territories be 100 percent smoke free.

Similarly, federal law should prohibit smoking on any bus, train, or cruise ship which originates or arrives at any point in the United States.

The federal government -- and that would include EPA, CDC, and NIOSH -- should complete a risk assessment of the cardiovascular health effects of exposure to environmental tobacco smoke.

Two: Economic incentives for smoke free work forces should be developed and, in short, should be encouraged to differentially rate work sites by their no smoking policies, including smoke- free work sites and opportunities for employee's smoking cessation for purposes of proving health insurance, business insurance, and worker's compensation.

Three: To complement the laws and regulations prohibiting smoking, as well as adoption of additional restrictions imposed by the private sector;

Adequate funds should be provided for a program of education and public awareness about the dangers of environmental tobacco smoke.

In addition to the above recommendations, the subcommittee urges the Full Committee to request immediately that the President sign an Executive Order making federal workplaces, including all branches of the military and the Department of Veterans Affairs hospitals, 100 percent smoke free.

We believe that such an action would demonstrate the continued support of the administration for a tobacco-free society. That concludes our report.

QUESTIONS AND ANSWERS

DR. KESSLER: Other members of the subcommittee?

Dr. Banzhaf.

DR. BANZHAF: If I might, on page two, there is language which suggests that regulation of smoking by the federal government may be less effective or less desirable than regulation by state or local jurisdictions.

I recognize there are often problems working quickly in transcribing this, but my memory is we didn't significantly discuss that or vote on it. I think it's not empirically necessary correct. Anybody who flies on an airplane or bus knows that enforcement of those no smoking regulations are pretty effective.

It also seems to be an inconsistent argument when we strongly urge and support the idea of federal control over the sale of tobacco products through the Food and Drug Administration because the states aren't effective, and then turn around and argue that somehow the federal government will not be effective in restricting smoking.

And, finally, I think there are advantages and disadvantages to federal, state, and local regulation of tobacco smoke. We ought not to try to figure out which is better. We ought to urge all of them without trying to single out one.

Thank you.

MR. GARRISON: Thank you, John.

Any other comments from the Committee?

Julia?

MS. CAROL: Obviously, there's overlap in some of these reports and therefore things can fall through the cracks. And I was on the Committee, and I was assuming that the Youth Committee would deal with the importance of educating youth on the issue of secondhand smoke as a prevention measure.

But that needs to now go somewhere since we didn't have it in here.

In addition, while I was sitting here, last night I found out that the tobacco industry has helped to introduce preemption into the Oregon State Legislature, so they are still fighting the battle. They are not quite on their feet yet -- on their knees yet.

And I'd like to add something, which would be that we all work to eliminate the existing preemption.

We've taken, in this report that we don't want future preemption, but I'd like to remove existing preemption.

DR. KESSLER: Other points? Dick, were you on the Committee?

MR. DAYNARD: Yes. I wasn't at the last meeting. I'm just wondering whether the intent at that meeting was that the restriction of smoking in all worksites, there is an exception in the proposed OSHA rules for separately-ventilated areas where nobody has to go in the course of his or her working activities.

Is it the intent of the remainder of the Committee, at least, that this exception appropriately strengthened to make sure that as much as technologically feasible or no ETS escapes to the rest of the workplace, that that exception remain in our recommendations, or is it the intent to eliminate the exception?

MR. GARRISON: John, do you want to comment on that?

DR. BANZHAF: Yes, we did discuss that, Dick. I think the feeling was that there are no technological ways to prevent the escape of air, even from separately-ventilated rooms, when those doors open and close.

Any attempt to try to come up with elaborate standards for that would be counterproductive, so the simple solution is to do with environmental tobacco smoke what we did with asbestos. You don't have it.

MR. GARRISON: This Committee took a pretty firm line in terms of making certain that smoking -- first of all, it said prohibit smoking, and we really didn't expect or want to see secondhand smoke anywhere in any public or workplace.

DR. KESSLER: Why don't we start on general questions, points of clarification.

Reverend.

REV. BROWN: I wanted to find out whether or not the Committee discussed a decrease in insurance rates beyond health insurance in terms of liability insurance and worksite as an incentive for part of the incentive program to become a smoke free workplace?

MR. GARRISON: We did not go into excessive discussion on that, Jesse.

DR. McCAFFREE: John, as you know, the VA hospitals are smoke free at the present time, but we're forced by the Staggers Amendment to build protected environments for smokers.

Are you suggesting that perhaps those protected smoking areas outside the hospitals be eliminated?

MR. GARRISON: We would like to see those smoking areas eliminated as well.

DR. KESSLER: This part of the table, any questions for clarification?

DR. WASSERMAN: Dr. Kessler?

DR. KESSLER: Yes.

DR. WASSERMAN: Just one question, again, for the group to consider. It sounds like a zero tolerance for environmental tobacco smoke.

MR. GARRISON: I think that's accurate.

DR. WASSERMAN: And I would just ask --

MR. GARRISON: And certainly in public places.

DR. WASSERMAN: Including, it sounds like, all of the air. I would just ask the group whether that's achievable, just to raise that as issue for the group to consider.

MS. CAROL: Can I just add a comment that we took our mission to be one of setting a vision for the future not just talking about what we're all proposing today, but trying to stay a step ahead of ourselves as the climate changes and the culture changes.

So we wanted to be visionary. This is the ideal world.

DR. KESSLER: But one of the caveats is that anything that comes out of this group has to be eminently reasonable to the American public.

MS. CAROL: Well, we thought the ideal world was reasonable.

(Laughter)

DR. KESSLER: Mr. Chairmen, if I could add, everything we've recommended in there is already in effect somewhere. There are bans on smoking on beaches, there are bans on smoking around buildings. There are bans on smoking in parks. There are many jurisdictions in many areas in Washington, for example, where buildings are totally smoke free.

So nothing that I understand we have recommended hasn't been done and is not in effect and working effectively somewhere.

DR. KESSLER: Let's move to this part of the table for questions of clarification.

(No response.)

Thank you, Dr. Garrison.

MR. GARRISON: Thank you, Dr. Kessler.

DR. KESSLER: Dr. Koop?

DR. KOOP: I think we all have the tendency when we're talking about tobacco control to focus on cigarettes. I would like to suggest that all of committees undertake a caveat someplace in their report that says they recognize that tendency and that all of the things we're talking about in reference to tobacco control applied to other areas of smoking tobacco, especially the tremendous new increase in cigar smoking, which is a great environmental tobacco smoke hazard, but also not to forget that we have the great problem of smokeless tobacco and to have caveats someplace that says that all of the things we say about the control of cigarettes apply where necessary and where possible to smokeless tobacco with appropriate changes, because of the type of material that's being used.

DR. KESSLER: Thanks, Dr. Koop.

John Seffrin, the American Cancer Society, chaired the Nicotine and Product Regulation Subcommittee.

Mr. Seffrin.

NICOTINE AND PRODUCT REGULATION SUBCOMMITTEE

MR. SEFFRIN: Good morning.

Mr. Chairmen, I'm John Seffrin, Chief Executive Officer of the American Cancer Society and chairperson of the Subcommittee on Nicotine and Product Regulation.

First, let me thank Drs. Koop and Kessler for their continued leadership in this effort to assure that we protect the health of all Americans against the killer, that is, tobacco.

I want to also recognize the quick work of our subcommittee. In a short period of time, we've covered a great deal of ground.

Matt Myers, Judy Sopinsky, Dick Daynard, and Bill Novelli helped frame this document, which we have to share with you today, and we owe them a debt of gratitude.

The charge of our work group is, indeed, complex, as it is for each work group.

Nicotine and product regulation is a huge area of concern and one that could feel reams of paper with ink. Yet we, as a Subcommittee, have worked to cull from that huge body of knowledge and information, six key areas for examination.

Those include addiction, research, FDA authority, information disclosure, and equitable regulatory framework and international considerations.

To do so, we also convened a technical advisory panel of what we think are some of the best minds in medicine, tobacco control and addiction research.

[redacted]Drs. David Burns, Ron Davis, John Slade, Gregg Connolly, and Jack

Henningfield helped our group hone in on the crucial components needed for effective regulation of nicotine and all that it must encompass.

Dr. Koop, I think our recommendations are ideally reasonable and reasonably ideal.

In short, it is our belief that the strongest and most appropriate health policy in the regulation of this deadly product will,

First, provide for treatment of currently addicted Americans, some 50 million in our population today, as you know.

The provision of that treatment, by the way, must be multifaceted. It must embrace multi-component treatment programs with proven efficacy, continued research for ever better methodology, and very, very importantly, we see that this should be a lifetime benefit.

Industry has produced a huge subpopulation of 50 million addicts, and we think it's unreasonable to expect that a once opportunity in a lifetime is not enough, it needs to be a lifetime opportunity to deal with that addiction.

Second: We believe that the strongest and most appropriate health policy in the regulation of this deadly project will fund research in order to develop less hazardous and alternative delivery devices.

Third: We believe that this nation's strongest and most appropriate health policy in the regulation of this deadly product will give the FDA immediate authority to regulate all areas of nicotine, as well other constituents and ingredients.

And we need to remind ourselves, as Dr. Kessler could educate us, that authority to regulate is not the same thing as effective regulation.

Now, between the authority and the effect comes empowerment.

So we believe full and proper funding of the FDA for such historic regulation is critically important to any national health policy on this issue.

Further, and fourth: It is the belief of our subcommittee that the strongest and most appropriate health policy in the regulation of this deadly product will force the tobacco industry to disclose all information regarding all aspects of the product, including, but not limited to, pricing, market data, content, toxicity levels, addictiveness, and ease of use.

This disclosure should include disclosure by other, shall we say, related organizations, such as trade organizations for the tobacco industry, law firms that represent them, and even their service providers.

Fifth: It is our belief that the strongest and most appropriate health policy in the regulation of this deadly product will foster a regulatory framework that is equitable and consistent with all other nicotine delivery devices.

In other words, in my language, no double standard. The same standards for alternative delivery devices as for tobacco.

Finally, six, but just as important as the other five, we believe: That the strongest and most appropriate health policy in the regulation of this deadly product will be mindful of and responsive to the international implications of our own domestic regulatory policy.

Now, we know that we have to be realistic and that there are limits, that the United States policy cannot, indeed, govern the world, but we do believe some very reasonable considerations, including such things as funding for international information exchange, as we learn, seems to be a moral imperative to share that with the rest of the world.

The development of uniform warning guidelines for products that are exported from our nation and such specific internal actions as the forbidding of the use of Section 301 of the Trade Act for tobacco, in terms of our own government promoting the industry's activities in the world marketplace.

Well, Mr. Chairmen, these touchstones provide, we think, the basis, a true beginning, we believe, for a comprehensive and effective regulatory environment.

I look forward to the dialogue we will have today and want to reaffirm the charge that I gave to our subcommittee.

We must set aside all that we know or think we know about the politically-charged times that we are now living in and focus on the goal that brings us today for consensus, that is, the health and welfare of our children and this nation.

Thank you.

DR. KESSLER: Other members of your subcommittee?

QUESTIONS AND ANSWERS

MR. SEFFRIN: There were four members of the subcommittee -- Matt Myers, Judy Sopinsky, Dick Daynard, and Bill Novelli. .

DR. KESSLER: Members of the Subcommittee, any comments or points of clarification?

(No response.)

Let's then move on to members of this committee and points of clarification.

Dr. Graham, sir.

DR. GRAHAM: John, you specify a number of 50 million addicted. Could you give us the breakdown of addiction by delivery mechanism, at least in round numbers?

How many do we believe are addicted primarily to cigarettes, how many primarily to smokeless tobacco products, other tobacco products, and then co-addiction.

Do you have that breakdown?

MR. SEFFRIN: We do not in our interim reports. We'll obtain that information. I don't have it, but one of the other subcommittee members may have a better take on that than I.

We'll attempt to get that, and that's a very good question, and I think it's a knowable, answerable question, and we'll attempt to do that.

Yes.

REV. BROWN: I wanted to know whether or not it would be appropriate for cigars, specifically, to be named, to come under regulatory authority as cigarettes are; and did your committee discuss or struggle with that issue?

MR. SEFFRIN: It was broached but not resolved, but I think it is a serious consideration for our Committee.

Mr. Banzhaf.

MR. BANZHAF: Yes. I was going to add an answer to the Reverend's question that Action on Smoke and Health will be filing before the end of the week a petition with the FDA asking them to assert authority over nicotine in both regular cigars and little cigars, as they now do over cigarettes.

Those of you who read the report will recall that they declined to do it at that time because they found little evidence that that was a major problem with youth, which is the area they were concentrating in.

The most recent CDC report says about 30 percent of kids, in fact, have used cigars in the last year.

Based upon that, we will be asking the FDA to do it, and that will start the clock running on the regulatory process.

MS. McGRATH: Mr. Seffrin, did your subcommittee consider any advertising issues with regard to the adult population?

I realize that there are First Amendment concerns and that the Youth Subcommittee had comprehensive recommendations, but particularly advertising targeted, for example, at women at ethnic minorities, adults, if there would be either any voluntary or any mandatory regulatory consideration of doing that?

MR. SEFFRIN: We did not. That was not on our agenda, but it was brought up that we needed to consider that. And, indeed, we do, but we have not, at this point, fleshed out that issue.

DR. KESSLER: Any other comments from this side of the table; any questions or elucidations?

(No response.)

Questions from this side of the table?

DR. KOOP: I might just add that there is a report coming out from NCI on

cigar smoking very shortly, which will bring it out into public knowledge and give us a much better handle on how to approach that issue.

DR. KESSLER: Jeff Nesbit, a question?

MR. NESBIT: I just had a couple questions.

Did your committee consider whether the FDA should be required to wait for a decade or more before they're able to regulate nicotine?

(Laughter)
MR. SEFFRIN: Where did that question come from?

The notion of the framework -- the regulation and the framework was that it should be able, empowered to do what can be done and can be defended, and the funding for the research in order to get there at the earliest possible time.

You'll see in our report that there's phraseology that's better than I just gave you, but we did talk about that and suggested that the notion of urgency is is that as soon as it's practical, the FDA should be able to move with respect to nicotine regulations.

MR. NESBIT: And my second question is, speaking of that research, did you consider what the proper regulatory aim should be, either a cigarette with nonaddictive levels of nicotine or perhaps a safer cigarette that delivers varying levels of nicotine?

MR. SEFFRIN: That was discussed, but I can most honestly say I'm not sure we resolved that question.

MR. NESBIT: Thank you.

DR. KESSLER: Thank you, Mr. Seffrin.

TASK FORCE ON THE FUTURE OF THE TOBACCO INDUSTRY

AND TOBACCO CONTROL EFFORTS DR. KESSLER: Mr. Pertschuk. Mike, thank you for coming to the table. This is the Industry Economic Committee.

Could I just ask that you list the issues, the general, broader issues, that your subcommittee did consider, because the title of the committee isn't as --

MR. PERTSCHUK: Yes. Actually, we changed the title of the committee, under your direction, Mr. Chairman, if you may remember --

DR. KESSLER: Right.

MR. PERTSCHUK: -- as the Task Force on the Future of the Tobacco Industry and Tobacco Control efforts.

Let me pass on that question for the moment --

DR. KESSLER: Okay.

(Laughter)

MR. PERTSCHUK: -- and tell you that the members of this task force are unanimous in their gratitude to you to giving us a hopelessly indefinable --

(Laughter)

-- unwieldy and --

DR. KESSLER: I think I just got the answer to my question.
(Laughter)

MR. PERTSCHUK: -- unwieldy and essentially impossible set of tasks and, fortunately, we had no time within which to perform those tasks.

And our revenge is a report which is easily three times the length of any other task force report.

Not only that, but it contains discourses on a variety of issues and substantially differing levels of specificity.

Of course, we recognize, the task force members recognized, and we met late into the evening last night, that the ultimate report of the committee, the combined blueprint -- in the ultimate report of the committee, the combined blueprint, the elements reflected in this task force's recommendations must be reduced to a manageable size.

But the task force doesn't need to provide background for the discussion to the Committee on several technical issues, some of which form the basis for specific recommendations and some of which don't.

The good news is that the task force members did reach consensus on the specific recommendations which are contained on pages 11 through 15 of the report and also on 18 and 19 of the report.

And I would note that because the international issues, or some international issues wee integrated into the task of this report, there is a separate section of the report dealing with international issues which did, John, draw upon the report which you put into the record, as well as we're fortunate, through the blessings of E-mail, to be able to draw upon perhaps a dozen or so international experts for their input, in addition to it.

And we did try to follow, Mr. Chairman, the dictate of making the international recommendations of those which a reasonable Congress, free of tobacco lobby, might seriously consider.

And, really, I urge the members of the Committee to look at the recommendations on those pages, 11 through 15 and 18 through 19, before we meet this afternoon.

And they really are so diverse that I'm not sure that it's useful at this point to discuss them but to return to them later on. They range.

Now, there do remain, among the task force members, serious concerns on

issues that are not reflected in specific recommendations, most notably, the role of litigation and cancer control.

The task force report, as instructed by your mandate to the task force, contains an extensive discussion of the probable impact of the wide range of lawsuits now pending, the discussion to which the task force is greatly indebted to Allen Morrison, our resource expert, who is in the room.

But some task force members are concerned that the litigation analysis needs to be far more comprehensive than the analysis in the report and drawing upon wider expertise in order to guide Congress' future deliberations, again, recognizing that such analysis can hardly be accomplished in five days.

In addition, the task force members believe that the final committee report should contain specific recommendations, supporting the role of litigation in tobacco control.

We have with us, again for discussion this afternoon, a paper prepared, again, earlier this morning, by Allen Morrison, responding to the task force's recommendations, that we provide some specific recommendations supporting the role of litigation in tobacco control, and we will share that brief report, also, this afternoon with the committee members.

In addition, task force member Daynard, in particular, is concerned that the task force report does not address the issue of whether the tobacco industry's exposure should be capped, whether there should be a cap on the amount of money to be paid out for all purposes by the industry.

And he has prepared proposed recommendations for the Committee, which again we believe should be addressed in the Committee's discussion this afternoon.

Other task force members, and this, I think, is a general concern, which I have some feeling applies to other task force recommendations as well; several task force members expressed the concern that in our wish to be comprehensive, we have set forth a range of recommendations of varying levels of priority without attempting to prioritize, and urge that the Committee, in its final report, make some effort to identify the highest priorities.

Still other task force members, and here I sympathize, took exception, not at the task force report but at the polemical rhetoric of parts of the report and urged that the language of the final report be framed in language designed to engage citizens broadly, not just those of use whose outrage at the tobacco industry is chronic and irrepressible.

(Laughter)

Finally, members of the task force wish that the final committee report will make clear both to Congress and the President that the blueprint we will propose will not be the last word in tobacco control.

But as in all such past blueprints, will need to be revisited again and again as we learn more, both about the most effective policies to reduce tobacco use and the most effective means to respond to the latest tobacco industry strategies and tactics to expand tobacco use.

The task force members volunteer to continue to work with you and the committee staff to help reduce the final digestible section of the Committee report on the task force topics, integrating the feedback and views of other Committee members.

I just want to add that, in response to your question to the first question about penalties and the ways of measuring penalties, the task force does have on page 16, does recommend a rulemaking process before FDA, with a series of suggested criteria for developing the level of performance-based penalties adequate to do the job, which we offer for the consideration of the Committee.

Also, let me, at this point, ask the other task force members if they have additions. 15. Page 15.

DR. KESSLER: Other members of the subcommittee?

MR. PERTSCHUK: Of the indescribable task force.

QUESTIONS AND ANSWERS

DR. KESSLER: Dick, do you want to make a comment about your sub-report? Is that a way to refer to it?

MR. DAYNARD: Minority report.

DR. KESSLER: Minority report.

MR. DAYNARD: Well, I don't know if it's a minority report, I think it basically had not had the time to be digested --

DR. KESSLER: That's correct.

MR. DAYNARD: -- by the task force. But my thinking on the subject, I mean, one problem is the earlier communications with the committee got lost at Northeastern and Cyberspace so I sort of came on late.

One point is that I think it's very important, and I think it probably might be wise to add at least an advisory capacity to our committee, at least one economist, because I think if we're talking about future of the tobacco industry, we're talking very importantly in economic dimensions.

I'm not an economist but I am a consumer of their work. I think, clearly, a central issue is how much money ought the industry to be paying.

And we can think of it in a number of ways. We can think of it, is there an optimal amount that should be paid;

Is there a minimum amount that should be paid; and,

Is there any reason why there should be a cap?

Now, this can be thought of in terms of the effect that the money they paid would have on the price of cigarettes and, therefore, on consumption, which is a very important dimension.

It can also be thought of in terms of the appropriate punishment for industry behavior.

Are the levels sought correct levels?

Is it appropriate? How much money, if any at all, is it appropriate for the industry to continue to be able to profit, at least by the American tobacco market?

I think these are important questions, partly empirical, of a predictive sort and partly normative questions.

There's also the question put in here specifically in terms of punishment, ought there to be any type of cap on punishment; do punishment goals cut against the goals of producing optimal levels of compensation and optimal levels of industry expenditure.

There's also a proposal I have drawing on the amnesty provisions, present in countries, like Chile and South Africa, suggesting that perhaps if the industry could obtain some benefit of amnesty from at least punitive damages by filing, all their most compromising documents in a public depository, say within six months of this meeting or six months of legislation, and before any particular piece of legislation, were they to do that, these documents would not be usable against them in litigation.

So I think there are a whole range of possible devices and concerns that I think need to be addressed in the report. I've made the first stab at it, and that'll be distributed this afternoon.

DR. KESSLER: Let me also ask: You also mentioned a, let's call it a pending, to be considered, sub-report. Is that the way to describe these? You said Alan Morrison also?

MR. PERTSCHUK: What they really wee were issues that were raised that had not been adequately addressed by the task force, and Alan Morrison has prepared at the task force's request a start of recommendations on the affirmative support of litigation as a tobacco control tool.

DR. KESSLER: Is it reasonable to ask Mr. Morrison to comment for a minute, if he's willing to come to the table?

MR. PERTSCHUK: Also, Mr. Chair, I am willing now to talk about, summarize the recommendation.

DR. KESSLER: But let's let Mr. Morrison just put on the record that thinking, and then we can go back.

MR. MORRISON: Thank you. As Mike said, I did it this morning. After finishing late last night, I sat down at my machine this morning, with many of the ideas that Dick brought out yesterday. A good deal less specific on it.

I guess I should perhaps accuse myself of being a litigation addict, since I've been doing it for 25 years, but I think it is an important and essential tool of tobacco control.

We have done many things through litigation that would not have been possible otherwise, from discovering information, from turning public opinion around, from bringing the industry to the bargaining table.

And the paper and four pages or so tries to lay out where we have come and where we can continue to go, and in essence says: Litigation will continue to be needed, not simply against the industry but also, with all due respect, to the Food and Drug Administration, there will come a time when the David Kesslers of the world will not be in charge of the Food and Drug Administration and we need to be sure that the laws that are in place will continue to be in force.

That, in essence, is what the paper says and goes into it in some more detail, but I think it would be premature to discuss it more now and take up more of the Committee's time, until people had a chance to look at it and we can comment on it.

DR. KESSLER: Alan, if you could just stay because there may be some questions of clarification of what you just said.

MR. MORRISON: Absolutely.

DR. KESSLER: We will not hold you to the specifics. If you can turn the mike back to Mr. Pertschuk.

I think, perhaps, if you would be ready, we would be willing to just go through and list, so people can focus very specifically on the recommendations.

MR. PERTSCHUK: I would be pleased to do that, Mr. Chairman.

There are actually three separate sections of recommendations, and I will describe them briefly.

There is a separate report on tobacco farmers, which was prepared by the American Heart Association by Scott Ballin and Rich Hemburg, under Dudley's direction.

On page 11, there are three broad recommendations. They are for the establishment of a high-level, Blue Ribbon panel, to have as its mandate a thorough review of the domestic and international tobacco growing manufacturing and marketing operations and trends of U.S. tobacco companies and U.S. leaf dealers, and it describes in detail what such reviews should mean.

There is also a recommendation for the establishment of an economic assistance and development fund, funded by the tobacco companies, and administered by the tobacco growing groups, and there is call for elimination of the federal government's economic involvement and support for programs and projects that relate to maintenance and expansion of tobacco production.

Then in Section 4 is the overall set of recommendations of the task force, which relate to the continuation of tobacco control, the movement infrastructure necessary to support tobacco control activities and to monitor the future of tobacco control efforts.

These include, first, on page 13, a broad statement calling for unambiguous,

non-preemption provisions in any federal regulation of tobacco, expressly denying the intent or authority from Congress to preempt the imposition of higher standards by states and local jurisdictions.

The second is a broad category with several subcategories of the necessity of continued funding for federal, state, and local government, and nongovernmental tobacco control activities, at levels equivalent to those in states, such as California, Massachusetts, Arizona, and Oregon, which have dedicated portions of cigarette excise tax increases to such efforts.

And Recommendation 2 lists a series of areas that need to be funded in order to continue tobacco control efforts.

This is really a section dealing -- and following from the discussion of the importance of maintaining the infrastructure, both government and non-government, of the tobacco control movement, which essentially has been instrumental in bringing us to the point where we are today and continuing effective monitoring, enforcement, publicity around tobacco control issues.

In addition, on page 14, Recommendation 3 deals with, broadly with the need for disclosure of all internal tobacco company documents, which bear upon the public health, including past and present acts to undermine public health.

And, again, there is a list of inclusions of the kinds of information needed to be disclosed by the tobacco companies.

Fourth, on page 15, is a provision that I mentioned at the outset, which is the proposal that the recommendation that performance-based penalties are important, but that in establishing the level of those penalties, there needs to be quite an elaborate fact-taking and rulemaking procedure, with the suggested criteria, in order to establish levels which do effectively provide the kinds of incentives needed.

Now, finally, Section 5 is a separate discussion of international tobacco control, the impact of U.S. policies on international control.

Those provisions were guided by a series of principles stated at the top of page 16. Let me just read that section:

The concern in counsel of public health advocates around the world is that U.S. advocates, in the process of promoting a US-based national tobacco program, take great care, first, to do no harm. And this means enacting no policies which undermine tobacco control efforts abroad or redirect the marketing aggression of U.S.-based tobacco companies abroad.

Second: Within the limits imposed by U.S. constitutional constraints, to seize the opportunities created by the current strengths of the tobacco control movement in this country, to help set a strong standard for other countries to follow; and,

Third: And, again, under your injunction of reasonableness, respectful of reasonable concerns that regulations must be applied to all tobacco marketers without discrimination; nevertheless, to pledge support for the worldwide adoption and enforcement of U.S. standards for the growth of tobacco, manufacturing and marketing by U.S. tobacco companies abroad.

Then on page 18 and 19, there are a series of rather specific recommendations, both for the support of international standard-making bodies and others, which are designed to carry out those provisions.

And that is the extent of our report.

DR. KESSLER: Thank you very much, Mr. Pertschuk.

Other members of the subcommittee?

Julia Carol.

MS. CAROL: I just wanted to add that I had another concern, which I believe was also shared, which is more of an overview concern that I'd like to see reflected in the report, which is that any measures which are taken to control the tobacco industry's interference and opposition to public health, ought to be done so in a way so they do not look as though as they've been defeated while they're alive and kicking, but rather they look as though they're alive and kicking while they've been defeated.

DR. KESSLER: Dr. Fielding.

DR. FIELDING: I think as a member of the subcommittee, Mike's done a wonderful job in trying to corral cats, and I think that probably the area that I think still remains the most difficult for some of us is the international issue.

While I, for example, agree in general with what's here, I have some questions about, for example, the excess profits, tax, that might be levied and stuff.

I think this is an area that really requires more additional work.

I think some of these very specific ideas, like an excess profits tax, really needs to be vetted a little more thoroughly before some of us can wholeheartedly stand behind that recommendation.

DR. KESSLER: Any other members from the subcommittee?

(No response.)

Why don't we start at this end and ask for clarification from the committee.

(No response.)

Dr. Koop.

DR. KOOP: We seem to have a lot of momentum, and it's now 10:30. The attorney general from the State of Washington is here to talk to us, as is Matt Myers.

Could I see if anybody feels strongly inclined that we must take a break at this time?

DR. KESSLER: Cameramen?

(Laughter)

DR. KESSLER: We promise we won't do anything.

DR. KOOP: You seem to be the only gentlemen with trouble here, Bill.

MR. NOVELLI: I don't have any trouble. I would suggest taking a break, though.

DR. KESSLER: Let's make it 10 minutes, please.
(Recess)

DR. KOOP: You remember my opening remarks. I said that we would suspend the discussion of the subcommittees and the debate about that to hear from some other people. That time has come.

Before you, at the witness table, if we can call it that, is the Attorney General of the State of Washington, Christine Gregoire, and Matt Myers, who is already known to us.

And they are going to make a report to us, I presume, about what's been going on behind closed doors.

At the end of that time, we will adhere to the same format that we did for the previous reports. If any have questions of clarification, that is perfectly legitimate to present to these people, but there will be no debate. Then when they have finished and you've satisfied yourselves that you've learned all you can under those rules, we will get on to the next item of business.

ATTORNEY GENERAL GREGOIRE

AND

MATT MYERS

MR. MYERS: If I could take the opportunity, I would like to introduce Attorney General Gregoire.

Our goal today, to come before the Committee, is to provide you an update, and informational update, on the substance of the talks.

It's not to serve as an advocate for or against an agreement, because there is no agreement. An outline of the agreement is not yet clear.

But our goal is, as we promised, to make sure that you have as much information as we can possibly give you during the ongoing process.

I'd like to say as a preliminary matter, for me, it really is an honor to be here, particularly, because three of the public officials who I have admired the most in my career happen to be sitting around the table with me.

Three individuals who have used their office to do more social good in the most self-effacing way, keeping their eye on how you best protect the public health, are here; and that's Dr. Koop, Dr. Kessler. And, for you, many of you, and unsung hero, Christine Gregoire, the attorney general of the State of Washington who, from my point of view, is one of the most able, thoughtful, caring and self-effacing public officials who I've ever had the honor to work with.

What we'd like to do is, Chris would like to give an introduction as to where we are in the talks, an overview of the talks, and then I will be happy to provide as much detail as I can about the exact the status of the public health issues in the talks, and then we're happy to answer any questions that you may have.

CHRISTINE GREGOIRE

ATTORNEY GENERAL, STATE OF WASHINGTON

MS. GREGOIRE: Thank you, Matt.

Dr. Koop, Dr. Kessler, and members of the Committee, it's a pleasure to be here today. On behalf of myself, and to indicate to you that, as of today, there are 39 states that have brought an action against the industry.

The latest to join was this morning, and that was the State of Maine and yesterday was South Dakota.

Troubled by what we saw happening with this industry, frankly, unlike any other industry in the country, attorneys general began some three years ago to start to look at the conduct of this industry to ask whether, in fact, there were violations of state law and federal law being conducted by them.

All of the lawsuits, then, have been brought by attorneys general, allege, among them, violations of state consumer protection laws.

And, in essence, what that has to do is unfair and deceptive advertising, in particular to the youth of America, as well as antitrust violations.

What that specifically has to do with is a conspiracy to keep from the public not only a safer product but information that is due and owing to the consumers of this country if they are to purchase and use a given product.

So each of the attorneys general have alleged a number of other allegations in their complaint, but those two are very together in all of them.

As we joined one by one to make the decision as to whether we could commit he financial and human resources to take on an industry who, typically with regard to legislation, has a scorched earth policy, each and every one of us have done so, believing, in fact, that we have the capability of bringing about a successful resolution, which fundamentally had to protect the children of this country and had to change the conduct of this industry to conform with the laws of this country.

We set out four fundamental goals:

First and foremost goal for us was to protect our children by stopping the marketing of tobacco to kids and reducing youth access to tobacco.

What we've attempted to do while at the table is to ensure that the marketing and promotion of this product to our youth, knowing full well that if we can addict a children, we can addict them for life, would be stopped for the future consumers of America and for the health of our children.

We want to put in place that which unfortunately was overruled by Judge Ostein in the Greensboro decision. We'd want to ensure that that jurisdiction of the FDA is put back in place, plus additional tools in the arsenal of FDA, to make sure that our children are protected.

Secondly:

We wanted to provide full disclosure to the public able the health effects of tobacco products.

We want full disclosure of past, present, and future documents in the possession of this industry with regard to not only the safer product, the addictiveness of the product, and the health effects of this product, so that consumers are well informed, as any consumer is entitled to be, before using a product.

Thirdly: We want to protect consumers by reforming the business practices of these tobacco companies.

It is important for us, we believe, to recognize that this industry has gone almost wholly unregulated for far too long.

It is time that this industry was regulated, no less than any other industry in this country, and that includes the FDA's jurisdiction over the product with respect to nicotine, tar, and other harmful components.

It is our goal, as attorneys general, to do what we can to ensure that for the future health of this nation that this industry comes about producing a nonaddictive, safe product.

Fourth, we wanted to provide relief to the states and individuals for their tobacco-related health care costs.

In each of the claims of the attorneys general, we have asked for reimbursement for the taxpayers of our respective states, for the Medicaid costs associated with the diseases of this product.

As well, we have private consumers who are attempting to bring actions on behalf of a loved one or on behalf of themselves, for they have suffered the disease of this product by the harm and unfair and deceptive advertising and lack of truthfulness of this industry in the past.

During these last few months, we have been involved in settlement talks. we have been here for approximately four months. It seems like 40 years.

But it has produced, thus, far, a very comprehensive set of objectives, specific objectives, to accomplish each and every one of those goals set out by

the attorneys general.

It has, in many respects, exceeded those goals that we set for ourselves, because we believe that, if given the opportunity, even if we couldn't get some of the things we want to accomplish by way of litigation, that if we can get them accomplished through settlement talks today, to save 400,000 consumers, to save the children of America from becoming addicted, that we will have served the country in a very positive way.

We want to dramatically change the culture of this industry. It is far too long that it has preyed on our children and been deceptive to our American consumers. We want them to comply as any other industry.

It is within that spirit that we have been at the table for the four months, but I will tell you that over the last two weeks our negotiations have, in fact, been more contentious and more difficult than they have from the beginning when we sat down.

And, frankly, that is associated with the two significant issues; for me, the most significant issue, and that is the FDA's jurisdiction over nicotine, tar, and the other harmful components of the product.

We think that that key, the key to that jurisdiction, unlocks the future health of America, of the most preventable diseases in this country.

So we will stand fast. If we do not accomplish that goal, we will walk and we will go to trial on behalf of the respective consumers and children in our states.

But today, as I left the negotiations and will return again, I can't tell you whether, frankly, I'm optimistic or pessimistic, because the positions have hardened, and we are at the most difficult stage we have been in in the negotiations.

With that, I'd like Matt, if it would be okay with you, to go into a little bit more detail, and then I'd be happy to take any of your questions.

MATT MYERS

GENERAL COUNSEL

MR. MYERS: The negotiations have focused, in terms of time, in large part, on public health agenda items.

As I've listened to the categories that have been discussed this morning, it's a little outline of the sort of issues on which these negotiations have focused.

They have been premised on a number of factors, despite references to global resolution, settlement talks, and the like.

The discussions have been viewed as this is the next step in the ongoing war against the tobacco industry and to protect kids and that no one should expect no matter how good it is, that this should be the end of the battle, even on the issues that are addressed, frankly;

That if at the end of the day, anyone walks away from an agreement, if one is enacted and thinks that we've won, then we will have lost; that this is simply, if there is an agreement, the next step in our ongoing battle.

Second: We've approached these discussions from the concept that the lawsuits brought by the attorneys general provide leverage, that they are tools for public health gains, and the goal in the talks is to figure out how we maximize that leverage and then, at the end of the day, to see whether or not that leverage has gotten us further along than we could by pursuing the cases; and if not, for the attorneys general to go ahead with their lawsuits.

And, third: While the pending trial dates prove an urgency to the discussions, we have tried to ensure that the top criteria is to do it right, to the extent possible, that artificial deadlines put pressure, but that pressure shouldn't prevent full and lengthy discussions of those issues, or an opportunity for subsequent entering of them.

The process, while incredibly flawed, has allowed us to do that.

And if an agreement can be reached, everyone recognizes that that agreement is just the next phase, that it then will come to the members of this committee in a range of the White House, Congress, and the public for a full and fair debate and airing.

This Committee's work on that, so far today, I find to be extremely useful.

Let me try briefly, without repeating what is in the handout that's been given to you, so that we don't take more time, because I don't want to do that, to give you a sense of where the discussions are.

Attorney General Gregoire properly said that we are down to hard issues on which there are broad-scaled disagreements of areas of civil liability and outstanding questions with regard to industry concessions on some key components of the Food and Drug Administration's jurisdictions.

If those can't be resolved satisfactorily, what we will have gone through so far will have been an interesting academic exercise and nothing will be presented.

To go through the topics and the discussion so far:

Youth access: We've outlined the specifics, to the extent possible. The goal was to take what the Food and Drug Administration did and try to build on it, not because what the Food and Drug Administration did was flawed but because its authority was limited in some areas.

So, therefore, we've done some things beyond, such as the elimination of all vending machines, moving tobacco products behind the counter.

But, more importantly, if you were going to focus on the differences, my guess is that it would be to try to come up with a compliance and enforcement mechanism that builds on what the FDA did, and our focus had been on a nationwide licensing system that would be administered, both by the federal

government and by the states.

And, most importantly, from our point of view, funding from the tobacco industry, so that both FDA and state and local officials would have adequate funds, not coming out of the current assets, to make sure that there was an army out there to enforce it.

With regard to advertising and marketing, most of the issues that were raised this morning have been covered and, again, while the discussions took place before the FDA's authority over advertising marketing was at least temporary curtailed by the decision in Greensboro, there has been no backsliding on that issue, and the FDA's rule was deemed to be a floor not a ceiling.

We rapidly moved on to things like the elimination of all outdoor advertising, no matter what forum, no matter where, including advertising inside that faces outward.

The elimination of all cartoon and human figures so that it's not just the Joe Camel on which we've all focused, but frankly the much more effective Marlboro Man, who preys on our kids.

And, most importantly, from my point of view, having worked at the FTC, so that in the future we don't have to wait nine years for an agency to stop a new character after its done its damage so that we can do it before.

We have addressed Internet advertising here as well.

One of the key things that we have tried to address here is something that would be otherwise difficult to do, which is to deal with the "what if" there is a First Amendment challenge by somebody outside the room, and that is to try to insulate these protections in case of First Amendment challenge.

I personally believe everything we've done complies with the First Amendment, but that doesn't really matter. What we want to do is make sure that any changes that are made are real, and we have come up with a mechanism of incorporating all of the advertising marketing provisions, both in consent agreements and in binding contracts that will be a condition of the consent agreement.

We are also working on a mechanism to ensure that the same rules would apply to parties who are not at the table, new entrants to the tobacco market or renegade companies who are simply, for whatever reason, not a party to the agreement.

Those discussions are going on, so that's hard for me to talk about particular mechanisms.

FDA had said when it first started there was really three prongs to a major attack: Access, restriction on advertising, and public education.

What FDA was able to do on public education was limited unnecessarily.

These agreements have focused on the creation of a very large fund, initially beginning in the range of a half a billion dollars a year, having looked at the data from California, Massachusetts, and consulting with advertising experts,

and then to come up with the sort of public education program that I heard described today, and are working on a mechanism to insulate it from the annual congressional appropriations attack or the manipulations of a federal bureaucracy of people not as good as Dr. Kessler and Dr. Koop are running the show.

Fourth, Congress has kept to its own domain the issue of health warnings so that FDA was not able to deal with those issues and, from what we can see, this Congress was not likely to deal with those issues.

So we have tried to address that, but health warnings are not a solution by themselves but as part of a comprehensive effort, seem to be a critical component.

As you can see from here, the discussions have taken liberally from what Canada has done, because they're light years ahead of us, both in terms of the language on the warnings and on the placement of the warning, so that the warning will be moved from its invisible spot on the side to directly on the front, on 25 percent of the front of cigarette package in the same stark manner that Canada has done, white on black and black on white.

Equally as important, from my point of view, that as the science develops and we've learned more, to move the authority to change the warnings from the domain of Congress to the Food and Drug Administration, so that as science goes, we can deal with that.

The issue of full disclosure is as important to us as it has been to everybody around this table.

The full details of that depend somewhat on how the civil liabilities issues turn out, and so it's a work in progress, but we have focused on two basic principles:

If there is an agreement, we cannot continue to have the tobacco industry deny the health effects of its products.

We cannot continue to listen to gummy bear analogies if we're going to have a focused-sustained effort nationwide, and that will be a precondition.

And, second: The documents that are currently in discovery and any other documents, need to be public so that the American public can know the truth on these issues.

Equally as important to those, what we've tried to do is to ensure that within the FDA jurisdiction authority and the way the documents are disclosed, that if there is information in there that has not previously been known, whether of a scientific nature or otherwise, that this agreement focuses on setting up processes for allowing additional change.

Too often in the past, solutions in the tobacco area have focused on specific change, a change in the health warning, a ban on advertising on TV and haven't looked to set up a system to ensure that future change can be made outside the political realm.

Much of what we've looked at with regard to FDA's authority and other areas

is to ensure that we have mechanisms in place to adjust whether it's the advertising rules, the youth access rules, or scientific decisions in the future based on information we don't currently have available.

The concept of performance standards is one that we developed in these discussions, and they received wide airing already.

Our goal in them was to make it economically in the tobacco industry's interest, to meet the youth target goals, and have come up with a formula, not perfect by any stretch of the imagination, not one that drives them into the ocean, but one that is designed based on the best available data, not provided by the industry but provided by the CDC and other sources, so that if they hook youth smokers and don't meet the targets, that they actually lose money instead of making money on that.

The issue of maintaining the army on the ground, state and local tobacco control activists, has been a specific topic of conversation, particularly for those of us who lobby to ensure that federal funding for these programs continue.

A condition of the agreement will be funding at much higher levels than the federal government has done to maintain that army of state and local tobacco control activists on the ground, so that this agreement really is not the end of the day.

The concern for smokers has been another focus in the development of a plan to deal with smoking cessation, not on a one-time only use, as somebody mentioned today, quite properly, but over a lifetime as well; the need for funding for it, the need for research for it, the need for a mechanism for ensuring that those who want to quit have a mechanism for doing so, whether it's their first-time try to second-time try, or fifteenth-time try, at no cost to them, and out of funds provided by the tobacco industry. They caused the addiction, they should cure it.

The issue of environmental tobacco smoke has also been on the ground, been discussed. And, as most of you know, the base from which we've tried to work was a bill introduced by Congressman Waxman which was very similar to what the OSHA rule was trying to do and build from there.

As we have said previously, as a political compromise, at this point in the discussions, and as I should say, everything is a moving target in these areas, that exclusions of non fast food restaurants, casinos, bingo parlors, and bars, have been discussed, critically, from our point of view, is that this provision, like many of the other provisions, will have explicit language saying that it's not preemptive of state and local activity, and the goal at the end of the day is to have less preemption than we currently have, if nothing is done, not more, and to ensure that the right of state and local governments and youth access, local advertising, environmental tobacco smoke, in a number of areas, isn't left ambiguous but is directly addressed as well.

Another topic that's been addressed is one that has been lifted from the area of environmental area where corporate polluters have been found, and it's based on basically, a whole nature of the corporation that goes on, to try to development enforcement standards, internal monitoring standards, oversight standards, for the wrongdoers, in this case, the tobacco companies, to provide

us with greater insight into their behavior as opposed to having to depend on them to tell us, as they never have done, what they're really doing on that area as well.

Obviously, the discussion of the Food and Drug Administration's authority has been, you know, a significant topic, and as Attorney General Gregoire said, that's still a topic being discussed, so there's a little less that one can say, except for the fact that we have all taken the position that the FDA asserted its authority over tobacco and nicotine as a drug and device and has chosen to exercise that as a device because it gives the maximum flexibility and that there can be no retreat from that under any set of conditions whatsoever.

The broad range of authorities that FDA has, that come automatically from that, need to be explicitly recognized.

The number of areas we ought to try to clarify the authority so that there is an ongoing debate if the FDA seeks to move. One of those is, for example, non-tobacco ingredients.

Massachusetts has developed a law for substantial disclosure of non-tobacco ingredients and the process for doing it and a process for revising nicotine yield testing, and that has been explicitly addressed the obligation of the industry to prove that it's non-tobacco ingredients are not hazardous under conditions of use as opposed to (unintelligible) has been explicitly addressed.

The need for dramatic reform of tobacco advertising with regard to lower tar, low tar, and all of the other deceptive, what I call, what we all call deceptive advertising of less hazards products, has specifically been addressed.

We would be kidding anyone if we didn't say the issue of total nicotine control has not been contentious, and that's one of those areas that it simply, at the end of the day, if it isn't resolved properly, there won't be an agreement for people to review.

If it is resolved, at least to the satisfaction of the negotiators, then that's an issue that will have to be up for discussion, as we see what results we can best come up with.

Finally, two issues, let me just briefly mention, which are only touched on in here:

International issues and civil liability issues, which have received much of the media focus to date. International issues are very tricky to figure out what you can do that's real, that doesn't just look good, but that is real.

One of the things that we hope, if we can do something that we would also encourage the administration, which has the power on its own, as well, to step beyond what a group of private parties can do and urge the administration on its own to take to the World Health Organization and the World Health assembly, the best of what we've done, not the worst, and urge that it be absolute minimum standards in areas where the WHO convention goes further to urge those be adopted worldwide.

We think that that's absolutely incredible. We would like to see if we can get funding for international tobacco control efforts because of how difficult

that is right now, but that's an area under discussion.

The question of civil liability is a very, very hard one. The attorney generals certainly have been talking about settling their cases in return for substantial payments of money and that can be used for public health in their states, as well as these public health issues.

Lawyers who have been representing the class action cases which focus on addiction have been using their leverage to try to deal with the smoking cessation-related issues, and the problems of current smokers in these discussions.

And then you come to the hard issues, which is the right of individuals who have been injured by the tobacco companies to sue.

Attorney General Gregoire properly states that the attorney generals have taken a very strong position on this issue, but this is an issue in which there is no agreement among the parties at the present time.

We all feel strongly, as I know everyone around this table does, that the rights of individuals to bring these cases, the rights of individuals to recover without caps on their recovery, is absolutely essential if we're going to have an industry that's held responsible.

But the details of that are ones in which there continues to be disagreement and descension, and so the best I can offer this Committee is that as soon as we all have a better idea of where that comes or whether or not that turns into the ultimate roadblock, we will report back to the members of this Committee and the Committee as quickly as we can.

I think we'd both be happy to answer any questions that we can.

Our goal here today was to inform, not to advocate. As I said, there isn't an agreement yet to advocate for or against, and we all reserve judgment on that and what we would ask everyone here is the question we ask ourselves every day is, if there is an agreement, you know, is it the best vehicle to reduce the number of kids who start, reduce the number of Americans who die, and does it provide us the best vehicle for holding the tobacco industry responsible for its behavior now and in the future.

That's a question that will have to be answered when we finish the process.

DR. KOOP: Well, thank you both very much. It's been very helpful.

QUESTIONS AND ANSWERS

DR. KOOP: I have a question to start with.

From what we gather from the media, one of the tensions is the imminent trial in Mississippi. Is that deadline indeed going to force you to stay within certain parameters, or will you be able to stay for discussions beyond that to a more reasonable conclusion?

MS. GREGOIRE: Frankly, Dr. Koop, what we have discussed as attorneys general

is, even if we were to reach an agreement in principle at this very moment, we are going to continue to try our cases because any agreement in principle by us would need to go to you for your review, to Congress for its review and passage, and so on, and we're not willing, frankly, to hold up our cases.

So, on the one hand, it's a pressure point, only because one of the significant negotiators at the table will have to excuse himself, frankly, along with his team of lawyers and go to Mississippi and try the case.

But, beyond that, we're not intending to delay the prosecution of our cases until and unless there is, in fact, a signed, final agreement, and that can't be done by the attorneys general.

DR. KOOP: David, do you have a question?

DR. KESSLER: I have several questions if you can bear with me, and they're really meant to clarify, to understand, with some specificity, the number of issues.

General Gregoire, you said that today the Food and Drug Administration, as I understand it, under Judge Ostein's decision, has the ability to fully regulate nicotine, limited only by the provisions of whether it's safe and effective.

MS. GREGOIRE: Right.

DR. KESSLER: Do I understand you correctly to say, when you said the attorney generals or you will walk, anything less than full ability to regulate nicotine as the agency has today, is unacceptable?

MS. GREGOIRE: That's correct.

DR. KESSLER: Second question: The industry has put a pot of money on the table. I don't know what that number is. Different media reports have different numbers. We use $300 billion, $350 billion over 25 years, just hypothetically? Is that a reasonable number to base my question on?

MS. GREGOIRE: Hypothetically.

DR. KESSLER: Hypothetically.

Out of the $300 billion that the industry has put on the table, what percentage would go to public health measures relating to smoking?

MS. GREGOIRE: Well, in essence, we have -- and I'll be honest with you and say that because of the contentiousness of the two issues that have stalled the talks as of today, we have not discussed monies for probably well over a month.

By far and away, as Mr. Myers puts it, we've spent most of our time on the public health piece, so there's no specificity yet. But what we're talking about in terms of adult cessation is to fully fund and to ensure that that's done, and we're looking to those outside the table for assistance on that, but we have talked in terms of a billion dollars annually.

DR. KESSLER: So I'm correct, about one-third of one percent, is that your answer, will go to the public health measures with regard to smoking?

MR. MYERS: Dr. Kessler, Attorney General Gregoire is right. That issue has not been specifically addressed with the industry, but the answer is no, that's not correct.

At a minimum, which you will see in any agreement, and I guess I've never done it by a percentage, so give me a second to let you know.

DR. KESSLER: Sure.

MR. MYERS: At a minimum, you will be talking at no less than 20 percent that will go directly to tobacco-related issues and you could be talking significantly higher.

DR. KESSLER: Could you help me follow that money?

MR. MYERS: Well, the difficulty in following the money is, as General Gregoire correctly said; because issues of dollars were put aside some time ago to directly address this issue, the issue of allocation of dollars were also put aside.

So what has gone on over the last month has been discussions within the group of attorney generals but not directly within the industry on that question.

But let me try to put a framework for you if I can possibly do so.

That would include funding for FDA's tobacco-related efforts. It would include funding for state and local enforcement efforts.

It would include funding for tobacco control -- nongovernmental tobacco control, sorts of programs like ASSIST and building on those sorts of things as well.

It would include funding for smoking cessation.

It would include funding for research into the questions of why kids start, what we know about kids start, what we can learn about treatment-related issues with regard to those sorts of things.

It will include significant funding for counter-advertising or public education-related issues.

I am hopeful that it will include funding to deal with the issues of tobacco farmers, and I wasn't counting that in the numbers, but I do think we have to look at that as part of the problem, and that if this is an opportunity to begin to address that, we ought to take that opportunity in a meaningful, direct way.

Hopefully, it will include, as well, funding for organizations who currently get -- nonprofit organizations who currently get tobacco money and whose policies and principles are at least indirectly compromised to free them from that informal kind of addiction, as well.

I'm doing this off the top of my head, so I apologize if I miss something for you.

DR. KESSLER: But my question was, I mean, as I understand the approximate numbers and certainly it's a moving target, but under your estimate you're dealing with 6, 7 percent of the money would go to the public health --

MR. MYERS: No, I said to you --

DR. KESSLER: 20 million out of the 300.

MR. MYERS: No, no. I said -- no, no, I said 20 percent.

DR. KESSLER: 20 percent.
MR. MYERS: I said 20 percent.

DR. KESSLER: 20 percent would go toward smoking-related --

MR. MYERS: 20 percent, tobacco-related issues. That's right. For public health and tobacco, but it would be directly. That's right. We have run those numbers.

DR. KESSLER: Let me ask, the federal government, obviously, has a considerable share of Medicaid.

MS. GREGOIRE: Right.

DR. KESSLER: If I were the administrator of HCFA and was sitting here and saw the attorneys general recovering the dollars on that, what's the plan on the federal government being reimbursed its share of Medicaid costs?

MS. GREGOIRE: Frankly, we've talked about that. In some states, as in mine, it's a 50-50 share, so any reimbursement back to my state, if it was solely for the purpose of reimbursing the taxpayers for Medicaid, 50 percent of that would be the federal share.

So what we've talked about is, frankly, turning that issue of what those dollars would be used for, should we be able to recoup them, over to the White House and to Congress, to determine how best to use those dollars.

DR. KESSLER: Let me just -- just several other points of clarification.

The issue of reforming corporate behavior -- is that a fair term -- and the incentives and the penalties; if you look at those penalties that are currently being talked about, what would translate into being passed on to the consumer, as far as an increase in tobacco, the price of tobacco?

The penalties that are being talked about, what's the magnitude of those penalties?

MS. GREGOIRE: We tried to parallel all penalties, consistent with what the FDA has by way of penalties currently, with the exception of a considerable greater increase penalty for failure to disclose content.

Any new additives, any new ingredients; failure to disclose that kind of information would be subject to a much greater penalty; otherwise, we try to

parallel the current authority for penalty purposes of the FDA.

DR. KESSLER: But I'm trying to understand the magnitude. You're using that as the incentive to change corporate behavior, and I'm trying to understand whether the extent of it will change.

At a certain quantitative level, the incentives change, and help me understand what that level is.

I mean, there are a number of goals that I read in the press that have to be met and a number of performance standards, as you said, were set.
Failure to meet that performance standard would result in how much money being paid and what would that -- I mean, actually -- how severe a penalty would that be?

MS. GREGOIRE: The issue of the incentives has to do with goals that we have set for the industry to reduce youth smoking.

We've used -- I think -- Matt may have mentioned -- the University of Michigan and CDC for our basis.

We've looked at reductions of 30 percent in five years; 50 percent in 7 years, consistent with that of the FDA, and 60 percent in 10 years.

We've used as the base of the population, not that currently but over the last years, to ensure it's a really meaningful reduction because of the inflated number of youths that have increased smoking since 1991.

What we've tried to do is say for every percentage point that they missed, they would be fine in equivalency of approximately $80 million per percentage point, which could lead to fines of anywhere between 1.5 to 2 billion dollars in any given year.

And how we arrived at the $80 million was we tried to look at the average age of a child beginning to smoke at 14-1/2, and carry that out to the average life expectancy of that individual with a factor quit rate, and ask ourselves how much profit would the industry derive from hooking a child at the age of 14-1/2 and disgorge them of those profits by way of a penalty?

DR. KESSLER: If they missed that goal, if they miss that, what would they simply have to increase the pack in order to pay, to pass that through to customers? What would it translate into?

If you take that $80 million and you divide it by the number of packs that are sold, what does it come out to?

MR. MYERS: A typical question to answer, because the $80 million is a hypothetical. It's based on a formula that will take into account population data in five years, right now.

And what the calculation was based upon was the life-time profits, so that theoretically they would lose money on smokers, at that level, based upon the best available data.

We actually haven't done it, taken it back to a per pack.

DR. KESSLER: You know better than anyone. How many packs of cigarettes sold in this country a year?

MR. MYERS: Actually, I'm going brain dead on those issues, so I don't. Why doesn't somebody else help me because I don't remember the right number.

DR. BANZHAF: What's the number? How many dollars?

DR. KESSLER: How many packs.

MALE VOICE: 24 or 25 billion.

DR. BANZHAF: $100 billion is roughly $4.00 a pack.

DR. KESSLER: 25 billion packs of cigarettes. There's an $80 million penalty?

MR. MYERS: It's not -- 80 million was the calculation that we did. It would be based on a formula, so it would be different at the time.

DR. KESSLER: But my question is, you were using that as an incentive to change corporate behavior.

MR. MYERS: Yes.

DR. KESSLER: $80 million out of 25 billion packs --

DR. BANZHAF: 35 cents a pack.

DR. KESSLER: $80 million over 25 billion packs. That's not a lot of pass through, right?

MR. MYERS: Dr. Kessler, the formula that was devised was designed to be based on the best calculation, using CDC and other data on the profit the industry makes off of a teenager.

So that at the end of the day, hooking more teenagers was not a profitable venture.

And the formula, as devised, was also taken into account, price increases, so that the industry couldn't continue to make more money off of it.

DR. KESSLER: But if they didn't meet that goal, it's a few cents per pack.

MR. MYERS: That's possibly right. That's possibly right.

DR. KESSLER: Let me ask just a couple of other points of clarification.

What documents, I mean, are continued under the current thinking, to be potentially withheld, not to be made public, that have been discussed?

What's the industry, in essence, not willing to make public?

MS. GREGOIRE: I believe, though we have not written a term sheet on this subject, I believe that there is an agreement that they will fully disclose all non-attorney client documents without exception, and we have said to them, at this point, that's unacceptable; that we need to see those attorney-client documents in any way, shape, or form, related to preying on children, to the health effects of the product, to the addictive nature of the product, and so on.

So that piece of the discussion has not concluded yet, and that is the outstanding issue.

DR. KESSLER: Two last questions, and I apologize, but again for clarification.

Has the industry agreed to a regulatory framework that will lead sooner, rather than later, to a nonaddictive, safer cigarette?

MR. MYERS: The best answer is that's still a topic under discussion, and as you're aware that's our goal.

DR. KESSLER: Last question.

Do you believe that retaining the right to seek punitive damages is a key public health objective?

MR. MYERS: Yes.

DR. KESSLER: I apologize for taking so much time.

DR. KOOP: Okay. I guess we'll start over here. Anybody from that end of the table, around here, who would like to ask a question for clarification, please, not a debate?

Dick.

MR. DAYNARD: Yes. As I read the term sheet here --

MR. MYERS: This isn't a term sheet, Dick, it's a brief summary.

MR. DAYNARD: Right. As I read the summary here, I see, I think for the first time I've seen in print, though I'd heard about it, that on this youth smoking target, while it's $80 million per percentage point, there's a cap of 20 percentage points, which as I understand it, means that if the industry fails its targets by more than 20 percentage points, there's no additional penalty, which would seem to provide -- and I'm happy to be corrected if I'm wrong -- a sort of perverse incentive, that if they really miss the target then they might as well really maximize their income from selling to kids.

Is there a rationale for this limit that I'm missing?

MS. GREGOIRE: Well, actually, we're not finished about that particular piece. That issue is tentative at this point.

What we've tried to do is parallel what we expect of the industry, paralleled with what we expect of the states, so we've set comparable goals of compliance

rates with the states of 75 for the first 5, 85 percent for 7, and 90 percent for 10.

And if, in fact, we the states miss our targets, we, too, will be penalized for every percentage point fairly stiffly, and we, too, will be capped at some point, and it will be comparable to any cap that is afforded to the industry.

We have had discussions this morning, before I came over here, about what that is, and we have not yet reached a firm agreement on that.

MR. MYERS: Dick, one of the other things to keep in mind, too, is that the penalties in that section are not the only solution.

I mean, the goal of the discussions, if there is one, is to ensure that the FDA has broad-ranging flexibility should the youth targets not be met to take any other actions it deems appropriate as well.

So the penalties are not, quote, "the total solution" but are only a small part of an additional set of tools that we hope that will be there, that otherwise wouldn't be there.

DR. WASSERMAN: What are the state targets that the states are going to be held accountable to and are going to lose?

MS. GREGOIRE: They are 75 percent in 5 years; 85 percent in 7 years, and 90 percent in 10 years. Those are compliance rates.

There will be a requirement that each state, in order to receive its enforcement and compliance dollars, will turn in a plan to the Food and Drug Administration of exactly how it will carry out that compliance plan, and it will be required to do inspections of retail outlets, to ensure that they are selling to underage smokers, and they have to have compliance rates that meet those targets or that will be penalized for every percentage point they miss it.

DR. WASSERMAN: Just so I understand what you're saying. You're saying the states are going to be penalized of the retailers fail to comply with the law?

MS. GREGOIRE: At the same time, we have a national licensing minimum program -- states, of course, can be tougher -- that will require a severe penalty structure put up, including potential suspension and loss of license for any time a retailer is found to have sold to a minor.

What we've tried to do here is tried to say that for far too long we've looked the other way, and we have not been tough on enforcement in each of our respective states.

We've been better over the last few years, but we have not been where we need to be.

We need to look at sale of tobacco products to minor, as deadly, or more deadly, then even sale of alcoholic product to minors.

So we want to be tough on retailers in terms of what their penalty will be should they be caught selling to minors.

We want to be tough on states. If they're not doing their enforcement responsibility in making sure that there is no sale to minors, and tough on the industry if they do not accomplish the goals.

Coupled with all the regulatory requirements that we will put on them, we believe that they can aggressively stop the sale.

In the corporate culture piece, we also have added a provision where you know today that when the industry wants their signs point up at a point of sale, they give incentive dollars to the retail establishment.

I don't know how many retail establishments you folks have visited where the product is sitting out front, easy prey for a youngster to steal it, and that area is purchased by the tobacco industry and, in fact, they give incentive dollars to the retail outlets to keep product there with a very purposeful reasoning behind it.

What we have done is we have said you have to give incentive dollars to retail outlets. No more for that, but incentive dollars to them only if they have an absolute clean record with regard to sale of minors, while product has to be kept out of the reach and out of the ability of any individual, including minors, to get access to physically.

DR. KOOP: Dr. Wasserman.

DR. WASSERMAN: Could I just ask -- first of all, I want to commend you and the other attorneys general for the activities that you've had on all of our behalfs.

To what extent have you been able to discuss international issues with the degree of specificity, given the focus that you would naturally have as a group of state attorneys general?

MR. MYERS: You're asking Chris, but let me answer that.

The state attorneys general have been concerned, have operated from day one on principle, which was the first operating principle of the document this morning, which is under no condition to do any harm, ensure that in trying to improve the status of the United States, that we do nothing that would work to the determinant of the international community.

Second: We have looked for ways that were meaningful, that you could actually address international issues, and as we've said, we've explored a number of ways.

It's difficult to come up with solutions, because many of them involve the good faith and credit of the U.S. Government taking ideas overseas, and our hope is that if there is ever an agreement that moves the ball forward in this country, that our government will do so and do so aggressively.

Third: We've looked at tools with regard to regulation of the industry itself, but have tired to be very realistic in terms of will we actually accomplish a public health goal overseas?

We've talked about things like mandatory requirements of products that are made in the United States, with regard to export rules;

And have tried to look at the issue of what happens if we do that, do these companies simply go up the corporate ladder and then down the corporate ladder and make them into Czech Republic or in some other countries?

Those are difficult questions. Frankly, it's an issue on which we've been trying to seek input from others for ideas, of things that we could broach that might be feasible, that might be done through this, and have looked for ideas for a while, and it's been a very difficult issue to come up with things that we think actually are both doable and workable, and have urged the administration itself to be looking at it so that it translates whatever we do as quickly as possible to an internal norm and standard.

DR. KOOP: Any other questions?

Reverend Brown?

REV. BROWN: Just a quick question.

I wanted to know whether or not menthol has also been discussed in the same nicotine has been in terms of full disclosure of its effects, its impacts, death rates being higher among menthol users.

And I particularly raise that question since we know a high percentage of African-American youth smoke mentholated cigarettes.

And we are not quite clear as to -- or at least I'm unaware of all of the information that may be available around menthol.

And if it is not, can it be included?

And is there something -- and, in the broader picture, can other ingredients, like menthol, like we've done with nicotine, be part of a process to be allowed to be studied, disclosed, or whatever in the future, as we learn of it?

MS. GREGOIRE: We've been trying to look at the product in a comprehensive way.

While we feel it's absolutely essential that there be reduction of nicotine so that it's not an addictive product, we also have looked at the fact that our ultimate goal is not to produce a deadly, nonaddictive product.

Our ultimate goal is to produce a nonaddictive, safe product.

And to that end, we have said that we really do want the Food and Drug Administration to be able to look at the entire product, every component of it, and the components in combination, every ingredient, to test every ingredient, to see whether it is safe, if there's any new, to test for old ingredients, and to test them in combination, and to able to reduce tar, in particular, and to reduce other harmful components, to drive the industry through incentives and through mandatory requirements by the FDA, to ultimately produce a nonaddictive, safe product.

So we've said we want the research, we want the best science to be brought forward on the subject, and we want it to happen as soon as possible.

So we've been looking at the product as a whole not simply looking at the nicotine issue.

MR. MYERS: Jesse, the issue of menthol has been raised, to be sure that there was no misunderstanding, that it was included in the ingredients about which there was concern.

The ultimate goal at the end of the day was for FDA to be able to make decisions, whether it's to reduce nicotine or not to reduce nicotine, frankly, base on science, based on what's best.

I mean, reading the FDA rule itself and the report, having attended a lot of conferences on nicotine, the answer is there isn't yet a scientific consensus that I've seen, one way or the other, and our goal is to make sure the decision isn't a political one or isn't a negotiated one, but at the end of the day is a scientific decision made, based on the best available evidence, whether it's to reduce nicotine or not reduce nicotine; whether it's to do it in a particular way or not.

And the same thing goes true with the other ingredients as well.

DR. KOOP: Any other questions on the vertical arm of this table?

(No response.)

Let's try the vertical arm over here.

DR. HEYMAN: I wonder if I could ask just a few questions. I'd like to ask if you have considered how you're going to monitor your youth use target goals and exactly what mechanism you'll use and whether they've been statistically validated, and who's going to run that program.

MS. GREGOIRE: We've looked at the model as the University of Michigan, and we've looked at their analysis based on daily usage over 30 days, as the basis, by which we computed the numbers for purposes of bringing about the formula.

I think there is general consensus at the table that, while the University of Michigan study and model may not be perfect, it is one that's been in existence for years, and it does provide us clearly the basis to look over the last decade for usage and to base our youth reduction goal of 30, 50, and 60 on it, which is a truer, we believe, indication of youth smoking, then if we were to use, for example, 1996, with the inflated number that we've had over the last five years.

So we think that's satisfactory, and that's the model that we've been using.

DR. HEYMAN: The concern there, of course, is that the Monitoring the Future study is based on kids in school, as you know.

MS. GREGOIRE: Right.

DR. HEYMAN: I guess my concern would be that the incidence of smoking is

presumably and, in fact, is demonstrably higher among youngsters who are not in school.

MS. GREGOIRE: Right.

DR. HEYMAN: How would you address that?

MR. MYERS: I think the answer is, there is no perfect study out there, and the goal was to try to be as specific as possible so that we didn't spend five years litigating with the tobacco industry over methodology before we can begin to do measurements.

In looking at the data that was out there, both the CDC studies and a variety of others, the University of Michigan study at least provides a reliable barometer to measure change, although not absolute figures in that respect and had the advantage of being a set of numbers that the National Academy of Sciences, FDA, and everybody else has relied upon for now, so that we can be sure when that year comes that we don't spend two years debating about the number before we can get to the proper resolution, recognizing its flaws and vagaries.

And we consulted with the folks at the University of Michigan and CDC, and a number of other people, just in general about what was the best survey data to use, what was the most reliable survey data to use, and to move from there.

MS. GREGOIRE: And, again, Doctor, if in fact more reliable information was developed by the University of Michigan or another source, I believe that based on the obvious continuing authority of FDA to improve on anything we've done, that would be clearly there, possible for them to do.

DR. HEYMAN: If I could follow-up on that.

The dollar number that you're talking about, as a person who really doesn't understand the magnitude of these numbers, is that a significant penalty?

I guess the question that I'm asking, $80 million for percentage point, and I understand how that figure was derived; is that a number that is a significant enough penalty to the giants and the tobacco industry to influence their behavior?

MS. GREGOIRE: Well, you must remember that, first of all, it far exceeds anything that attorneys general have had by way of a continuing kind of penalty, if you miss goals in the future, and I look at a number of cases.

We've taken on the oil industry, we've taken on some of the largest corporations in this country.

Secondly, today, they're subject to nothing in terms of penalty for a fine.

And, thirdly, we didn't want to just arbitrarily set a number, and we grappled over this issue for a considerable period of time.

We didn't just want to say, okay, for every percentage point, or for every child or what have you, we wanted it to translate to them in a way that we meant

business, which is, you hook a kid, and we're going to disgorge you of all profit that you would get from hooking that child over the life of that individual. So we felt it brought meaning to the table.

I can tell you, at least at the table, it has been very contentious and, as a matter of fact, has managed to surface itself again this morning, as I think I indicated to Dr. Kessler before coming over here, in which they're saying it's just too onerous a penalty, coupled with the annual payments that they would be required to make on top of it.

So, again, is it enough for this industry? I really can't give you a meaningful answer.

Is it derived out of something that is meaningful; i.e., we will disgorge you of every profit for addicting a child? I believe it is.

DR. HEYMAN: And my last question: Given the history of the cleverness of the industry, have you addressed the issue of ultimate nicotine delivery systems and devices which might not come under FDA regulations?

MR. MYERS: We've tried to. You know, operating under a principle to the extent that we can, was to make as few changes in FDA laws, so that we run the least risk of doing something harmful.

We've done a number of things.

One is: Discuss requirements of them disclosing technology that they develop or acquire so that they can't pigeonhole it in any way, shape, or form.

And, two: Talked in terms of trying to encourage the development, whether by this industry or by the pharmaceuticals industry, alternate devices, don't run the same risks that traditional tobacco products to, how that will shake out, is still an open question.

DR. KOOP: Yes, sir. Dr. Fielding.

DR. FIELDING: I just have two questions. We've heard a lot about this formula and the incentives. Obviously, one of the areas in which there seems to be agreement is the desire to align incentives here, of the industry with public health interest.

I wonder if it's possible that we could understand and see what the formula is, the basis of it, or is that something that would not be possible to reveal at this point, so we could understand the assumptions that have been made, what it's accounted for or not?

MR. MYERS: Dr. Fielding, the answer is, as soon as there is something that has been formally agreed upon, and we can move to the next stage, yes, that'll be among the things that we'll immediately disclose, as Attorney General Gregoire said, as frankly the industry.

We're the ones who produced the formula. It was the attorney general's office that ran all the computer runs and collected the data for it.

The industry, now that it's running its own numbers on it as well, has told

us

(A) That our numbers are low, that the penalty, in fact, when they calculate it, much higher; and,

(B) Is now still wrangling about that.

So as soon as that is done -- and we are anxious, frankly, if we can reach an agreement, to move the entire process to the next stage, where the detailed descriptions of these things, including these sorts of formulas, can be made public so that the members of this Committee and everyone else as well, can look at them in detail.

You know, ultimately the devil is in the detail. Have you tied it down accurately enough?
And we're as anxious as you are to able to disclose that information to get that sort of input.

DR. FIELDING: Given the fact that that came basically from you and is not necessarily part of something that was agreed on, you said there's some contentious issues that are remaining.

You know, the more information that could be provided a priori would avoid problems down the road, and so I would urge that whatever is possible to be reviewed in terms of assumptions that you've made not the result of discussion, be surfaced so that it could be discussed by this group.

And, secondly, I wonder if you could just explain why you think -- as I understand it, if there is a settlement, there is somewhere between -- oh, I'll just throw out numbers -- 60 to 100 billion dollars that might be used for broad public health purposes.

And I just would like to understand why you feel that, in that context, that having the punitive damages, retaining punitive damages, be a make or break issue for public health.

MR. MYERS: One can't predict what will happen with the punitive damage issues. It's been widely reported in the press that it is a very contentious issue for both sides.

From our side, it's a matter of principal and social justice as much as it is money; that under any set of circumstances, if there is an agreement, there will be an assurance that tobacco industry will pay billions of dollars for its past wrongdoing, whether or not the court system works better in the future than it has in the past.

But at the same time, we have felt it's important that even if -- that an individual's right to go after punitive damages -- despite the fact that punitive damages aren't meant to compensate an individual, they're meant to punish a wrongdoing, seems to be a core issue for individuals, in that as you try to balance the needs for social justice, for public health gain, you can't ignore that very real and honest feeling.

At the same time, there are lots of people who believe that it would be a

mistake to let this deal, this agreement, fail because of that issue.

I think the best answer that we can say is, at the end of the day, that's a judgment that the American public is going to probably have to make, rather than us.

MS. GREGOIRE: Doctor, maybe I can help a little bit on that.

First and foremost, we think it's absolutely imperative that there be no curtailment of punitive damages for any future conduct.

We have to have a threat over this industry.

And, in fact, I'll be honest with you and say the track record of the private consumers in litigation against these companies is not very good thus far, as you probably know, and in no instance has a punitive damage award been given.

I believe that you will find that punitive damages are much more viable against this industry in the future because not only would you have the allegations but you would have, more likely than not, a violation of a regulation, which heretofore wasn't present.

Once you do, in a civil trial, have an industry that's violated a regulation, that does serve as powerful evidence for an assessment of punitive damages.

So future punitive damages are exceedingly important to all of us.

The issue of punitive damages for past conduct is a tough one for me as attorney general for Washington State, because we don't have punitive damages in my state, and I'm not unlike a number of my colleagues.

The social public policy underpinning of punitive damages is to accomplish two things:

One is to fundamentally change the conduct of a defendant in a case; and,

Two: Is to financially punish them to the point that it hurts.

We believe, at this point, in terms of fundamentally changing the conduct of this industry, we've made tremendous strides, based on what's on the table.

I don't know that we have accomplished the second, and that remains outstanding.

DR. FIELDING: Thank you.

DR. KOOP: Do you have any questions?

MS. CAROL: I have several questions.

First of all, it's my understanding -- and forgive me, I'm not an attorney -- that none of the Medicaid cases are seeking damages or recoverative costs for health problems associated with secondhand smoke. Is that true?

MS. GREGOIRE: Right.

MS. CAROL: Okay. Therefore, in the settlement, would anything preclude future recovery of those health care costs?

MS. GREGOIRE: By private consumers, you're talking about?

MS. CAROL: No, by the states, for Medicaid. There's numerous studies that show that, in fact, secondhand smoke has cost us a great deal as well.

MS. GREGOIRE: Very clearly, the issue of secondhand smoke has been on the table. Otherwise, we wouldn't have been able to negotiate the issues that we have currently with respect to putting in place a ban on public facility smoking.

I suspect that any recoveries that we make will have to cover that particular issue, as well.

MS. CAROL: So have you taken into consideration the costs?

MS. GREGOIRE: Yes.

MS. CAROL: Secondly, in terms of, then, can I follow from that -- and I don't know if this legally follows, but in my mind, it logically follows that the disclosure requirements would also be about industry research and --

MS. GREGOIRE: You bet.

MS. CAROL: -- effects to countermand efforts to protect the public from secondhand smoke?

MS. GREGOIRE: You bet.

MS. CAROL: Okay. How would the settlement, if there was a settlement, affect future litigation regarding criminal wrongdoing?

MS. GREGOIRE: From the day we began our negotiations, we have stood firm there will be no discussions of any immunity whatsoever with respect to criminal culpability, either by local country prosecutors, by state attorneys general or by federal authority.

MS. CAROL: And the industry has agreed to that?

MS. GREGOIRE: We don't have -- we won't settle on it. We won't discuss it. We've told them it was off the table.

MS. CAROL: But, I mean, is that a matter of contention --

MS. GREGOIRE: No.

MS. CAROL: -- or is that understand?

MS. GREGOIRE: No. They knew from the beginning it was not to be discussed.

MS. CAROL: Okay.

Next, in this draft from the Center, which I appreciate and wish I'd had sooner, it seems to me as if some of the things that you've been discussing today, in fact, the tobacco industry has agreed to various things, I'd like to know specifically what things in this paper are, you know, not agreed to yet or are contentious.

MR. MYERS: What we tried to do is to show where there was ongoing discussion and disagreement as of the time that we drafted it. So, for example, under civil liability, under the FDA's authority, we've reflected that.

DR. KOOP: Any other questions?

MS. CAROL: I just have one more. That is -- and this is in the legal sense, as well, that I don't understand.

I've never heard of anything this big being thrown together into one pot and sent to Congress, so I may not be the only one who doesn't understand.

Say there was a settlement reached and you got everything that you wanted and it made it through this Committee and we were all very happy, and it went to Congress.

What is there to prohibit the cigarette companies or their associates, people who work in the fields of advertising, marketing, retailers, et cetera, from lobbying Congress to put more, as Matt said, devil in the details?

MS. GREGOIRE: Well, we have some provisions that are still under negotiation with respect to that issue, and implicit thus far, at least in so far as my advocacy is concerned, is that in the consent decree, I want a provision that if, in fact, there are fundamental changes, first and foremost to FDA's jurisdiction over the product, that as far as I'm concerned the deal is off, and I proceed with my litigation.

So we intend to address that issue. It is not yet completed but we intend to address it by means of the consent decree.

MS. CAROL: I just have one more quick question, I'm sorry.

MS. GREGOIRE: I'm sorry. A consent decree is the document that we would enter into our state courts which would allow us to have continuing jurisdiction to make sure that this industry carried out in full exactly what we've negotiated at the table.

The reason why a consent decree -- we always use a consent decree, but the reason why it's important is I don't want to have to in the future, when there's a violation, start up a new case and have all the fight over jurisdiction.

I would have continuing jurisdiction in my state court, which is very important to attorneys general.

Secondly, as Matt indicated to you, on those issues that might be contested as unconstitutional, one can voluntarily waive one's constitutional rights, and by virtue of the consent decree, we would be able to enforce, for example, if someone was to have it pronounced that the ban on billboards was

unconstitutional, we would still have authority in our respective states, under our consent decree, to enforce against the industry.

That's why the issue of a consent decree is so important to us.

MS. CAROL: Okay. And, lastly, who would determine, how would it be determined if the goals for youth smoking are not met, who would determine whether it was the fault of the state or of the industry, and how would the blame be shared?

MS. GREGOIRE: It's no fault. If they're not met, it's the fault of the industry. They have to achieve the goal.

Now, they can come in and argue that it's somebody else's fault, but it's FDA who ultimately has the authority to assess the penalty against the industry.

MS. CAROL: I thought you were talking, as well, about states have penalties for --

MS. GREGOIRE: FDA has the authority over the states if they meet their noncompliance, as well, but in terms of --

MS. CAROL: What I'm saying is, whose noncompliance is it, the states or the industry's, and who decides?

MS. GREGOIRE: Well, the youth smoking reduction goal of 30 percent of youth, that's the industry's, and the industry will be held fully accountable to achieve that goal.

MS. CAROL: Thank you.

MR. MYERS: FDA is the decision maker.

DR. KOOP: Other questions on that arm?

(No response.)

DR. KOOP: If not, we'll go to the horizontal arm here.

Dudley.

DR. HAFNER: I think it's appropriate just to follow-up in the question.

With a 20 percent margin or cap in the penalties for not meeting -- making targets, I heard something earlier that if they didn't meet them but they were outrageously off target, or words to that effect, that they could then profit, is that, in fact, a true statement? Is that a possible outcome?

Am I being clear with my question?

MR. MYERS: Yes. sure.

Because there is a cap, albeit it a high one, so that the annual penalty if you reach the cap would be in today's dollars, somewhere between we thought it was somewhere between 1.6 and 2 billion dollars, but apparently the industry

thinks it's higher under the formula, if youth smoking rates didn't drop at all, then the penalty would not be adequate to fully compensate or fully withdraw all profit under those circumstances in the hope that, at that point in time, would be that the industry's behavior will prompt FDA and other regulatory authorities to step in with a strong a hammer as it has, to look at the reasons why and to take whatever action is appropriate.

You know, the performance standard is not the total solution. It is a piece of the puzzle. It was designed to add to the arsenal we have right now. It isn't the perfect tool.

MS. McGRATH: In your discussions, have you considered the topic of adult advertising? I know we're focusing on youth advertising, which I think everyone agrees is very important. But adult advertising targeted particularly to particular groups remains a concern.

Has that come up or eliminating the targeting of particular groups?

MR. MYERS: Well, it is a concern, and one of the reasons for the discussion about things, like billboard advertising, is to prevent the industries from continuing to be inundated, whether it's adults or kids.

One of the reasons for getting rid of the images was because of all of the preliminary influences on kids. You would also like the imagery associated with that to disappear.

The same is true with the elimination of all advertising in sports stadium and other public events.

It's also our, frankly, and one of the things that we've talked about, is that the public education or antismoking campaigns will, as important as youth smoking is, be broad-scale campaigns and that they will be localized to deal with both different community issues and different demographic issues so that they can be most effective in reaching every target population.

DR. KOOP: I would just mention the chairman's concern. It's not 12:00. Could I ask, in order that we can finish this morning's agenda, not going over too far, that the questions be crisp, few, and the answers the same?

DR. BANZHAF: A widely-quoted claim is that the plan, at least as it was presented last week in an invitation-only press briefing, would save 1 million lives of kids.

I'd like to know, is there anything behind that claim? Is there a study which documents it? It is based upon research?

Does it take the various components of this proposal as it was outlined last Thursday and measure their relative benefits and, if so, can we get it?

MR. MYERS: Much as the FDA did when it set a target of 50 percent, and then try to evaluate what its impact would be if you succeeded, it's my understanding that that's what was done in this case, that was done by the American Cancer Society, and I don't think there is any secret to how it was done, and to the extent that that's possible, I'll --

DR. BANZHAF: Are there any documents behind it?

MR. MYERS: I don't have a document but I'm happy to look to see if there is one. There's nothing secret about how that was done.

DR. BANZHAF: The second quick question: According to my math, an $80 million penalty would be roughly one-thousandths of the income of the tobacco industry.

Now my guess is that most of us around the table wouldn't be very deterred by a penalty of one-thousandth of our income. Why would you assume -- is there any data to suggest that it's going to have an important effect on the tobacco industry?

MR. MYERS: The best I can answer, John, is that we've tried to come up with a formula to strip the industry of profit it makes from addicting kids and a formula that would be factually and scientifically based along those lines.

Whether it's going to be enough, quote, "to deter them" or to punish them, is a question we're going to have to leave to others. It was designed to strip the economic benefit of attracting those kids from them.

DR. BANZHAF: I would like to join in congratulating both of you for your work and your presentation.

DR. KOOP: We have a quick answer to John's question from John Seffrin.

MR. SEFFRIN: Very quickly. As many of you know, the American Cancer Society has conducted two huge prospective epidemiologic studies, call Cancer Prevention Study No. 1, done in the late '50s and early '60s;

Cancer Prevention Study No. 2, done in the '80s, and ongoing.

We're tracking 1.2 million Americans until they die, and we have arguably the best and most reliable data set on being able to extrapolate and estimate the impact of tobacco on populations.

Those data were used over a period of time at my request by our Department of Epidemiology and Statistics to determine if the targets were reached, in particular, the 60 percent reduction in 10 years, how many current children below the age of 20, lives would be saved during their lifetime?

If the children, the 3 million that take up smoking, half of them later quit, it would save 750,000 lives. If they continued to smoke and didn't quit, it would kill 1.5 million. The midpoint is 1 million lives saved.

We think it is a reliable estimate and I've given a handout that all of you should now have before you, that gives you the way in which our department derived those estimates.

I will say that Richard Peto at Oxford, England, has used the same data set to project the impact of tobacco in other parts of the world and has been widely published since 1994.

DR. BANZHAF: Thank you.

DR. KOOP: Any other questions?

MS. SOPENSKI: I keep hearing reference made to looking at the FDA as a starting point and making sure that those standards would be enforced.

Now, in the past year, you know, since 1996, we've already seen very significant changes in the marketing and the promotion and the advertising of tobacco products that clearly meets FDA regulations, but the industry has altered its tactics already.

I'm thinking, in particular, about the cigars and the way they have been promoted, which has not had a youth focus at all but has resulted in a significant use in youth use.

My question is, where will the flexibility to adapt to the industry's changes come in to play? MR. MYERS: Judy, as you know, FDA has not asserted jurisdiction over cigars. Nothing in this agreement would limit its authority to do so in any way, shape, or form if it felt it had that authority, and obviously, as the evidence mounts, our organization will, everybody at this table, I'm sure, do what we can to encourage, that if we believe the statutory standard can be met for cigars, we encourage the FDA to do so;

That we ask the FTC to look at cigar advertising to the extent that it focuses on kids and that we use every weapon in our arsenal to do so.

MS. GREGOIRE: And we've made sure that with respect to advertising, I'm acutely aware of the skepticism that you have, and that's why, for example, point of sale, we've tried to address everything conceivably they've done in foreign countries to get around some of that.

That's why we think learning the lessons of the past of how this industry adapts to new things, we have made sure that FDA has continuing jurisdiction should they do something that surreptitiously gets around what we intend to have accomplished;

Or if, in fact, what we've done doesn't accomplish what we want, that FDA can come in and make sure it's done right in the future by changing whatever is necessary to accomplish the goal.

DR. KOOP: Yes.

DR. HOUSTON: Thank you, Mr. Chair. Three quick questions.

First, as relates to the class actions. There has been wide report in the media that class actions of not only Costano style cases but the airline attendance case and others would be negated by the proposals, and I wondered about a clarification on that.

MR. MYERS: The airline attendant's case will be not touched by it at all, no matter what happens. And there have been discussions in the future about class actions.

DR. HOUSTON: Secondly, you mentioned, Matt, a couple of minutes ago that the agreement covered images in tobacco advertising.

In the document you've handed out, it just talks about human images and cartoon characters.

Given the industry's imagination regarding images, that seems to be a shortfall.

MR. MYERS: In those places that are deemed to be adult-only publications, as the FDA defined that, they would continue to be able to use color imagery as the FDA would have permitted them to do.

What we will be able to do is to eliminate it from the billboards and the other outdoor areas, which they have used so successfully in England and other countries, to circumvent the impact of restrictions on human images and cartoon characters there.

But it does mean that, to the extent that they're using color and imagery in adult-only publications, newspapers, magazines, and those places that are permitted under the FDA Rule, that they will continue to be able to do so.

DR. HOUSTON: Final question. You mentioned, Attorney General, that the states would be held to certain standards of performance regarding youth access and other issues.

The implication is, then, that the industry wouldn't interfere with your ability to do your job.

Has that been discussed at all?

MS. GREGOIRE: Yes.

DR. HOUSTON: That is, that the industry activities that get in your way would cease?

MS. GREGOIRE: We have discussed not only that but the deplorable experience that I personally had in my legislature this past legislative session, where I believe they did everything to lobby through a bill under the guise that it was to make children responsible and, in fact, what it was intended to do was let retailers off.

And we've talked at length about how to curtail that kind of activity in the future and what penalties would be provided, should that kind of activities occur.

DR. HOUSTON: Thank you.

DR. KOOP: Any other? Bob.

DR. GRAHAM: A single question, I believe, to Ms. Gregoire.

Consent agreements. You've described this morning that they are central to your strategy. I'm trying to understand the leverage and vulnerability of those agreements should a settlement be achieved.

I'm not a lawyer and, therefore, I do not deal with them frequently.

It sounds like consent agreements would have to be entered into state by state with each AG and might vary state by state.

I am also wondering what the vulnerability of consent agreements are. Can they be challenged by third parties?

For instance, we are talking, under the terms of the settlement that you've outlined, with marked changes in the retail availability of tobacco products.

Could retailers ban together and challenge a consent decree between the AG and the industry because of the changed economic climate for them?

Are consent decrees subject to overturn by the U.S. Congress?

MS. GREGOIRE: The latter one is a tougher one than any of the preceding questions.

DR. GRAHAM: Okay.

MS. GREGOIRE: Our goal is to ensure that Congress is able to pass a comprehensive act to get a handle on the industry, but we want also to be able to have a back-up document, and that's what it's intended to be.

That's enforceable at the state level with continuing jurisdiction by a state court.

What that means, for example, if there is a violation of the consent decree, and the consent decree would incorporate, in total, the agreement, if there was a violation of a term or condition of that consent decree, automatically the state court and in a very short period of time, can not only provide us with injunctive relief to stop the activity, but also find some penalties on them.

But if there's further violation, it would be a violation of then a court injunctive order subjecting the defendant to criminal prosecution.

That's why consent decrees, as you can imagine, are so important to us.

Could the United States Congress overrule consent decrees entered into by the respective attorneys general of this country? We do not believe so.

(Laughter)

MR. PERTSCHUK: Yes, I have a question of future process, in addition to all of the other things for which we are grateful to you; one is the addition of a new term to my lexicon, which is term sheet.

The question I have is if your negotiations do conclude and you move to the second step that Matt talks about, what exactly is it that we will see in terms of paper, the term sheets, the material, the agreement itself? Will there be proposed legislation, and what will we have to evaluate?

MS. GREGOIRE: Well, all of this is moving at this point, but what I think you will be provided is if there was an agreement in principle, a term sheet would

have to be.

A term sheet is not the most specificity but, nonetheless, a high degree of specificity about what we're talking about.

Clearly, clearly the term sheet with regard to the public health piece will, by far and away, be the most specific of any of the term sheets.

You will find a term sheet, I'm sure, on enforcement and penalties, a term sheet on financial recoupment back to the states and into the federal government, and a term sheet with regard to liability.

Then, from there, that term sheet would have to be used as the basis for a detailed, comprehensive congressional act to be developed, but you would be given, if we were able to agree in principle, that term sheet from which to comment.

For purposes of your folks, I think it would have all of the specificity that would be of assistance for you to comment back before the legislation is actually written up.

MR. PERTSCHUK: Thank you.

MR. MYERS: The goal in the drafting of the document is to ensure that it includes as many details as humanly possible. It is, in part, being used as a check to make sure that our understandings we agree to are the same as their understandings and there aren't things left unsaid so that at the end of the day two different folks don't look at the same paragraph or sentence or concept and come up with different factual conclusions about what it means.

MR. PERTSCHUK: Thank you.

DR. KOOP: One final crisp question from Dr. Kessler.

MR. NESBIT: Actually, I'd like to.

DR. KOOP: You have one.

MR. NESBIT: I just had one question.

If an agreement is reached and consent decrees are entered, do you believe any of the attorneys general will forestall their cases, their action, while it's pending in Congress and the White House?

MS. GREGOIRE: No. As I indicated earlier, at this point in time, the discussions that we have had as attorneys general this week, in particular with respect to Mississippi and Florida, is that they would move forward on their litigation.

Now, there's obviously one other alternative, which is that they could settle their individual cases, but short of that, and there has been no discussion of that, we will proceed to litigate our cases while anything is pending in Congress.

MR. NESBIT: And you believe that's fairly uniform among the other attorneys general?

MS. GREGOIRE: The five of us that are the negotiating team have talked about that and agreed that that's the position we want to take at this time.

We have a conference call with our colleagues set at 4:00 today to discuss that today as well.

DR. KESSLER: Yesterday, the BAT chief was quoted in a major newspaper as saying they want to be paid off and we want a peaceful life. That should give anyone pause, obviously.

Sitting across the table from the industry, do you believe that the industry is ready to support, in good faith, a reduction in the number of smokers over the next several decades in this country?

MR. MYERS: Dr. Kessler, we've operated on the assumption that if that turns out to be the case, that would be obviously a plus, but that an agreement has got to be based on a premise that an industry that's behaved this way would otherwise behave that way, and therefore the goal in the agreement is to come up with strong mandatory rules with as crisp mechanisms for enforcement as humanly possible.

Then if, in fact, the industry chooses to use this opportunity to change is behavior, we will have a net plus, but in the event they don't, we will still have moved the ball forward as far as possible.

DR. KESSLER: The agreement, then, would have to be rock solid?

MR. MYERS: Our goal is to make it as rock solid as possible. I mean, will it be perfect? Certainly not.

Will it be the best that we can do in that respect based on the assumption that whatever we're told in the room, and we're obviously told lots of things about using this an opportunity to make fundamental change, and they profess that and they say it, and they say it in ways that if you didn't study their history you might otherwise believe.

(Laughter)

That our goal is to ensure, whether or not that's true, that at the end of the process we've done something that moves us towards our goal, and then if it turns out to be true, well, that's just a plus from where we are.

MS. GREGOIRE: We will not take this industry on faith.

(Laughter)

MS. GREGOIRE: The people sitting across the table, by the way, are not industry. They are not industry. So it doesn't matter to me what the people sitting across the table from me tell me today. These are people who are legal counsel on behalf of the industry.

I will not take this industry on faith. I wouldn't take them on faith even if I didn't know their 40-year history.

But knowing their 40-year history, I have no intention whatsoever to take them on faith and, in fact, that's why, in looking at lessons learned, it's not only important that FDA have full authority but it also have full authority to correct any errors that we may have made in thinking that we're going to get it done the way we set forth, and we didn't make it happen. We want to make sure.

But, again, as I've said to this industry, I'm not asking anything from you I don't ask of every other industry in this country. It's just time that you played by the same rules everybody else has had to play for the last 40 years, and you haven't.

DR. KOOP: Thank you both very much.

MS. GREGOIRE: Thank you.

HUBERT HUMPHREY, ATTORNEY GENERAL

MINNESOTA

DR. KOOP: Our next speaker is the Attorney General from the State of Minnesota, Mr. Hubert Humphrey.

While he's coming to the table, I want to tell you a conversation about some questions that were asked of me yesterday by some members of Congress.

I don't want you to think that that's how I spend most of my afternoons, but I did yesterday, and that it did give me some pause.

And they said, have you give any thought to the tremendous pressure that's going to be put on Congress if there is a tobacco settlement by other industries that are adversely affected by that settlement decision?

They were talking not so much about what they could in the long run but the tremendous delaying tactics for any legislative procedure.

Mr. Humphrey, we're delighted you're here, and the floor is yours.

MR. HUMPHREY: Thank you, Dr. Koop and Dean Kessler, and all of the distinguished ladies and gentlemen that are here. I appreciate the opportunity to visit.

I will try and meet the most significant challenge of my life, and that is to hold back Humphrey genes, since we are all kind of at that time of the day.

The one lesson I think I learned from father was you don't make long speeches in front of lunch or dinner.

(Laughter)

But this is, of course, a very real and serious concern that you are addressing today.

I commend by colleague, Chris Gregoire, and her colleagues that are working hard on this matter.

I certainly commend Mr. Myers and others who are at the table and doing their very best to see that change takes place.

I commend all of you for being here to take very serious review of the concerns of the highest order to this country, the nation's health.

It's terribly important. This is the number one health issue that we have to address, and this is the time for us to begin that addressing.

So I really appreciate the opportunity. It would be very hard to overstate the importance of your role.

We stand here today at the most decisive moment in America's 300-year love-hate relationship with tobacco.

I was reminded this morning at an earlier meeting with a former Congressman. He said, take a look around the hall.

All those leaves that are up there on those ceilings and all around, they're tobacco leaves. So we ought to understand that this product is imbedded deeply in our culture and our nation's history,m and to make the changes in both attitude and reality is going to be very, very difficult.

For the first time in that entire history and, undoubtedly, for the last time in our generation, we are on the brink of achieving enduring solutions and to the most pervasive, most pernicious health problem of our time.

In large measure, your work will determine whether America seizes that opportunity or whether, instead, we squander the chance of a lifetime on well meaning but inadequate answers.

It is not an exaggeration to say that today you are the guardians of the health of our children and grandchildren and of our parents as well because this struggle must be about the children and the more than 50 million addicted adults in this country.

Now, that's a heavy responsibility, but one that I know you take very seriously and one which I believe you are well prepared to meet.

Many of you have spend long years in the trenches of the tobacco wars.

Some may be relatively new to this subject, but I trust that all of you are aware of the painful history of America's well intentioned but naive and fruitless efforts to bring this industry to bay.

Time and again, over the decades, we have thought that victory was ours. We have toasted their defeat only to learn some years later that we were bamboozled once more and that the tobacco industry had cried all the way to bank.

Now 30 years ago we celebrated, when we forced these companies to put the Surgeon General's warnings on the pack, only to learn that they desperately

wanted those warnings in order to protect them in the courtroom.

We celebrated when we forced them to take their ads off television, only to learn later, by eliminating all of the counter-advertising, we actually helped them.

Every time we think we have danced on this industry's grave, they have, instead, found a way to keep the dancing on those of our loved ones, by the hundreds and the thousands, and we have to keep that in mind.

Ladies and gentlemen, in my office, we enforce consumer protection laws of our state, just as my colleague, Chris Gregoire, and every other attorney general, and every day hundreds of consumers call us about questionable deals they encounter in marketplace, whether it might be the shady real estate deal, a high pressured used car sale, or a crooked telemarketing come on.

We tell them four things, and I hope that you will keep these in mind when you review any so-called tobacco mega deal.

First: We tell them get it in writing. Golden promises count for nothing.
Second: We tell them read the fine print. The sales pitch may sound great, but does the fine print give away what the headlines have promised?

Third: We ask them to watch out for the high-pressured hard, fast sell. You know the ones. Where they'd say, "You've just gotta do it now, or it's gonna go out the road."

We tell them to be suspicious of salesmen who say you have to sign the deal today and you can't take the time to think about it.

Finally, on fourth, we tell them, when it sounds to good to be true, it probably is.

In fact, that's often the best warning signal that it's time to get out your magnifying glass and the fine tooth comb to find the hidden dangers.

If caution isn appropriate when a consumer buys a car or takes out a mortgage, how much greater should the caution be in order when we deal with the greatest public health issue of our time?

We're counting on you to help us through this, not just to analyze and critique the sketchy proposal that's been brought forward, or what we know of that proposal; we're looking for you to help us think through, in the broadest sense, what this industry should look like when we win the tobacco wars, and that's why, Mr. Chairman, I appreciate your effort to make that blueprint and to lay out the requirements.

Now make no mistake about it. We are winning in this effort and we need to keep on winning. We are wining the legal skirmishes, we are winning the public debate and, more importantly, we're winning the hearts and minds of the American people.

The only thing that can hold back the power of public sentiment is a deal that declares another false victory.

The industry can only achieve that victory if we are lulled into complacency or if we fail to ask some very tough questions, and obviously this morning you have already begun that questioning.

So we are counting on you to ask the hard questions and take time to get the answers.

Let me suggest just a couple of other questions, I think, that you should consider.

First of all ask: What's the rush? Every day a new development that strengthens the public's position is shown. In the next 7 months, 4 states will go to trial. If anyone is worried about the strength of those cases or about who should be first up to bat, I've got to tell you that any one of us will take the first up to bat, Minnesota included.

Our trial is set for January 19th of next year. If others would prefer to delay or whatever, we're willing to stand up. We want to tell a jury about the things that we have found among the industry's secret documents.
As our counsel has said, they're not just smoking guns, they're smoking Howitzers.

Some people think that all of the important information is already out. I'm here to tell you, it isn't out. The depth, the pervasiveness of this conspiracy and fraud is overwhelming. There has never been anything like it.

I believe we owe a fundamental duty to the future generations to see this through to make sure that we don't settle until all of the information is before the public.

The task force chairman, Mr. Mike Pertschuk, this morning said, "As we learn more." Well, let's be sure that we have the opportunity to learn more.

Because of our court's orders, I can't talk about all the things that we're doing, but I can tell you that I read a newspaper report yesterday that says our attorneys deposed the former research director of Philip Morris on Monday, and that he took the Fifth Amendment.

Without my commenting on the accuracy of that report, I want you to just think what will happen to public opinion, just a few months from now, if senior tobacco executives start parading before juries and showing up on the evening news, invoking the Fifth Amendment whenever they're asked about whether they buried the technology to make cigarettes safer or how they manipulated nicotine.

At that point, perhaps the industry will be ready to sign a real settlement in the public's interest, not just on the industry's terms.

Now please understand. I do realize that time is of the essence because kids start smoking every day as has been well stated here this morning. I am not arguing that we should sit back for years until all of the appeals are existed and the endless litigation that might go on, but I do hope you will remember that if we take just a little bit longer to see that the American people have

all the facts, we won't need the tobacco industry's permission to hold it to the same rules that govern everyone else.

Now, if we take just enough time to get it right, America can make the rules, and we won't have to trade away the rights of victims or the powers of the federal government to fashion a real solution.

That will save a lot more kids than locking ourselves into 10 or 25 years or more in a horse trade that guarantees this industry a profitable future well beyond our lifetimes.

Now, second, I would hope that you would insist that all of the facts come out.

I saw some bullet points of a deal last week that described what was supposedly agreed to. I was distressed to see serious proposals to let the industry off the hook by only disclosing their internal scientific research documents.

This is a good example of why we need to be suspicious of shorthand or bullet-point summaries that you will be getting. It needs to be fully explained, and I'm glad that Attorney General Gregoire indicated, and certainly Mr. Myers indicated, that as much as open as possible would be here. I think that's very helpful.

What this proposal would do in reality is let the industry keep the secret documents that count, the ones that they have hidden, the most important evidence about their products, the documents they've hidden all of these years behind the claims of the attorney-client privilege.

That's where the truth lies, including the truth about scientific and medical knowledge. Those are key documents. They've never seen the light of the day.

Now, we're on the verge of getting some of them, and most of them, if not all of them, in the Minnesota case. Our judge in our court has ruled that the Court's Special Master will be reviewing 500,000 pages of these documents to see which ones hold evidence of fraud, and which ones are attempts to bury crucial medical and scientific evidence that has been hidden for decades behind a shield of phony privileged claims.

In a sense, ladies and gentlemen, while we have 33 million documents, that is the haystack. We are getting to the proverbial needle in the haystack. These are the documents that the industry least wants anyone to see.

This is obviously something that you should care about, and you really have to ask the question, or is it just an issue for lawyers?

Let me give you an example.

When Liggett and Myers and settled with the states last spring, it agreed to drop the claim of privilege on its documents. That will give us a peak behind the privilege veil.

Our Minnesota court, as I've said, is still sorting that out, but last week,

Congressman Waxman released a Liggett document which had been hidden for 30 years that revealed that they had spent $13 million to develop cigarette technology that virtually eliminated tumors in mouse-paining experiments. But they buried the research.

If Liggett was finding things out like that, what has Philip Morris got?

Should we really consider a settlement that says they don't have to tell us, that they can shred their documents instead? Obviously, I think all of us would say no.

Third: I hope that you'll ask some tough questions about the money, as you already have. As far as I'm concerned, any settlement that sends tobacco stock soaring, can't be a good deal for our country.

The leading Wall Street expert says Philip Morris stock will go up some 40 percent if we accept the deal present under discussion. I think there's something wrong with that picture, folks.

The experts tell us this industry can afford hundreds of billions more than any figure currently on the table. Experts say they can easily pay $2 a pack compared to the figures being discussed, which would work out to perhaps 50 or 60 cents a pack.

And the leading expert, Professor Jeff Harris, of MIT, tells us that the first $2 a pack is essentially free to the industry because they'll pass it along in higher prices and won't even feel any pain unless the price is more than $2.

So I hope you'll ask how much they could afford and how much they ought to pay. And, of course, keep in mind that a higher per-pack price of cigarettes can lead to significant reductions in smoking, especially among young people.

And I hope you'll ask whether any settlement places all of the burden on addicted smokers or whether the companies themselves ought to bear some of that burden in the form of interrupted dividends or sale of assets, or secondary stock offerings, rather than merely shifting it to their customers.

I hope you'll ask whether the proposal does justice for the victims who have lost their health or their lives to this deadly product. I hear the proposal would bar class settlements, class action settlements, which would isolate and impoverish any individual claimants foolish enough to challenge the world's most ferocious litigation opponent.

This would virtually guarantee that there will be no future impact litigation. Now is that right or is it necessary? Those are some of the issues that you have to address.

As I understand it, the proposal would guarantee the industry that it would never have to pay more than $4 billion a year to its victims, even though the CDC tells us that the victims suffer about $100 billion each year in medical costs and economic loss.

Now, over time, with inflation, those losses will be 200 to 300 billion a

year, but the proposed settlement would apparently shelter the industry beyond a guarantee that its losses would be limited to $4 billion.

I hope we're going to be asking whether that's enough.

Now, I could go on, but I think you get the point. This is not the time for false urgency. We need to slow down and get it right. We need your committee to take all of the time it needs to think carefully and thoughtfully and anything we set in place now will not be visited in our lifetime, so we need to get it right.

Now, as public health leader and advocates, I hope you will consider some key areas when looking at any deal, which I raised to my colleagues in a letter dated May 2nd.

Does the settlement preserve full FDA jurisdiction over tobacco products and content, including nicotine?

Again, I am pleased to hear the assurances that have been said at this table this morning, but I have to urge you, the devil's in the details. Watch the word nicotine. There's all sorts of words that go around it. What are we doing with regard to FDA jurisdiction and its regulation of tobacco and nicotine?

What will a settlement do for the nation's 50 million addicted tobacco users and do about rising smoke rates, especially among teens? And you have already raised very interesting questions about that.

Is the deal enforceable through the courts? I, like my colleague, Ms. Gregoire, absolutely believe in the court orders. I want to see that in Minnesota they are going to have to deal with the order that the court brings out and brings forth.

Will the Tobacco Institute and the Council for Tobacco Research be allowed to continue their activities? We want to see them curtailed and wrapped up.

Does the settlement incent the companies to develop less dangerous products? Well, should we dawdle? Of course not. But we've squandered every opportunity that has come along in the past. We've lost 30 years and allowed this industry to bury millions of Americans because we didn't take the time to get it right. Let's not repeat that mistake.

Let's help America decide objectively and with a clear eye whether any settlement proposal is truly worth buying today or whether we should do what it takes to get all of the information, create real reforms and set a fair price for all of the harm that's been done.

I believe you have the capacity to do this. I believe you have the public's attention to help the Congress and the nation come to grips with this. It is terribly important the work that you do.

And I want to thank you for allowing me to come and visit with me this morning, and I'd be more than happy to answer any questions.

QUESTIONS AND ANSWERS

DR. KOOP: Could you take as much as 10 minutes, Mr. Humphrey?

MR. HUMPHREY: Oh, sure.

DR. KOOP: Let's have the questions again, Chris. Mr. Humphrey has to be at the White House very shortly and so we will not keep him longer than 10 minutes longer.

Let's start where we left off before.

This arm, this arm, that arm, and that one.

Bob.

DR. GRAHAM: Your message is very clear that, in your judgment, now is not the time to settle. You're going to kill them in the courts. Kind of like Joe Namath, you're guaranteeing a victory.

MR. HUMPHREY: Oh, no.

DR. GRAHAM: Our job, obviously, is focused more on public health policy, rather than the settlement, but the settlement is what you're talking about.
It would help me if you could critique your own position, as we are trying to weigh when's the right time and when's the right settlement.

You have articulated a very strong position, in my view, that now is not the right time for any settlement.

What will you be watching in the attorneys general cases that go to trial before yours that we should watch, that may send us a single that we may not kill them in court, and that settlement may be the best public health approach?

MR. HUMPHREY: Let me back up for a moment. I want you to understand that the vast majority of cases that we bring in our state and we do a very active practice of both consumer protection and antitrust litigation, the vast majority of those are resolved through settlement, but that settlement comes at a time when both parties have all the information.

They are able to weigh the strengths and the weaknesses of each side. Many times, they come at the direction of the Court, which says, get together, try and resolve this. Sometimes it happens when you're in mid-court, when you're in trial, and there is a matter for resolution.

I just firmly believe that we have not yet gotten all the information out.

It is not the appropriate time, at this point, to be making those settlement decisions. The other thing is we need to know the whole picture, what is being offered, what are the details?

Those are the kinds of things that we need to take a look at.

The other thing I have to tell you is this: Is that I firmly believe what Mr. Lincoln said is correct, try and settle your cases; there are plenty of others to litigate. I am one that will be willing to try and settle, but I am not

afraid to be in court. And I believe that the tobacco industry knows that we are fully prepared to go to court, to deal with it at trial, to let the public, through jury and through the public process, get all of that information.

There will be a time and a place, and I'm not saying it's just January 19th. Obviously, we're dealing with a great number of different cases. I would ask you to watch very carefully.

We have learned from some of the cases that have already taken place, some of the individual, private cases. There's been two in Florida already.

We have learned from the case that was in North Carolina. There were those that said "Settle" before that North Carolina case.

We now have the direction from the District Court that says that the FDA has full authority.

We have learned from the case that was brought by the City of Baltimore that they, indeed, have the right to regulate and ban if they want the billboards all over that city.

So I would measure by watching carefully what happens and, as the matters come to fore and we have all of the information and we secure that information for the future generations, then I think there's probably going to be a time to sit down and resolve at least our own private cases.

But when it comes to the public's interest and the public's health policy, I think that's where your forum is, and I think you have the prime effort to make that decision.

DR. KOOP: Question from this arm?

(No response.)

Nobody. Over here. Jonathan.

DR. FIELDING: There are two kind of information that we might get. One is the disclosure information.

Could you see a situation where if one took the worst case, and all the worst fears and ideas one has about practices came out to light, and you put those on a piece of paper, and you said, we have a deal that even if all that came to light and was true, that that would make sense, we would still wind up at the same place.

Would that not be a useful metric to use in thinking about that kind of information?

MR. HUMPHREY: Well, it might. But I think what you're trying to accomplish here by establishing at least a structure with which -- you know, we hopefully have bright lights and can see way down the road, and that's why the talent that is in this room is so vitally important to developing that blueprint.

First, we need to have that blueprint. I don't believe we have that in

place.

To the extent that settlement negotiations are encompassing these issues, we need to have your energy shining brightly on that.

Then we also need to have the ability to turn the corners that we can't quite see, and that's where the FDA, full regulation authority, comes into play, so that to the extent, as was said earlier here today, that we can't anticipate what changes are necessary, we need to be able to have that flexibility. The public needs to have that flexibility.

We should not, through trading across a negotiating table, limit that process. And I would assume that Congress will not allow that to happen, not without very serious consideration and deliberation.

DR. FIELDING: Secondly, are you suggesting that part of the timing not being right now is simply because we have had not had, we should await more of the disposition of the court cases?

MR. HUMPHREY: I don't think that's going to hurt, and I can tell you this, and I want you to understand; the order that we got from our Court, the Court didn't change the trial date. We're going to trial on January 19th. We are going to get more information.

I would say that at least we need to know that kind of information. Now, obviously, those documents are presently under a court order. I would hope at some point this depository and repository of information is held sacrosanct for the public and for researchers to be able to use, so that we can least learn from past history.

That's something that has to definitely be worked out in detail.

DR. KOOP: Any questions over here?

(No response.)

Any other questions?

(No response.)

DR. KOOP: Thank you very much. We appreciate it.

MR. HUMPHREY: Thank you. I appreciate the opportunity to be here.

DR. KOOP: Shall we break now for lunch, ladies and gentlemen. Be back here at 2:00.

MR. NESBIT: Before you all break, I just want to make sure that people understood that we did invite the tobacco industry, their representatives or their lawyers, to come and update this panel as well, and they declined to do so.

(A luncheon recess was taken.)

A F T E R N O O N S E S S I O N (2:18 p.m.)

YOUTH SUBCOMMITTEE

DR. KESSLER: For the afternoon session, we can start with the Youth Subcommittee. Dr. Heyman, if you would be kind enough to -- maybe it's more comfortable to go back there, and feel free to bring any staff that you want next to you.

What we would like to achieve is to make sure that Dr. Heyman and the other members of the Subcommittee have all of your issues.

To the extent that we can reach a consensus on what Dr. Heyman proposed this morning, I think let's try to do that. But the real goal is to make sure you have everyone's issues before you so you can consider that in the preparation of the final product.

Are there any recommendations on how to divide up the Youth Recommendations? We all have in front of us the eight-page document. You have subheadings here. Promotion, advertising, public education, fiscal, research issues. Should we go through them in that order very quickly? Is that a reasonable breakdown?

Why don't we do it that way, and why don't we start with the policy recommendations under promotion as well as the enforcement recommendations.

Do you want to just briefly, while people are just scanning it, in 30 seconds summarize the high-priority issues that you think you would like some more input?

DR. HEYMAN: I think the most important and stunning aspect of this recommendation, to me, is whether this committee would be in favor of an outright ban on the advertising, marketing, and promotion of all tobacco products and services, goods and other items that carry tobacco brand names, logos, or imagery.

I think that's a piece of guidance that our committee would like very much to hear from the assembled group.

DR. KESSLER: People's views?

Mr. Seffrin.

MR. SEFFRIN: Clarification. Total ban?

DR. HEYMAN: Yes, sir. Total ban.

DR. BANZHAF: There was the article in the Wall Street Journal just about a week ago which showed how even where you have total bans on such things the tobacco industry can get around bans on advertising of tobacco products by advertising either cigarette cases or lighters or whatever else.

It's happened in Finland, it's happened in Norway, it's happened in many other countries. So I think if you simply limit the ban to advertising or promotion of tobacco products, it is going to be largely as ineffective here as it was in those other countries. Therefore, I would say "go for it."

That's certainly the experience of other countries. Indeed, some have actually gone on to what we now call third-level laws. Because they banned advertising tobacco products, the tobacco industry go around that by advertising, again, cigarette lighters, cigarette cases, and so on. So they banned that, and then they found ways around that, also.

So, at very least, we ought to go to the second level, if not the third level.

MR. MYERS: Fortunately, the FDA Rule already dealt with the ways they circumvented it in Finland and other countries, because it already bans advertising on those sorts of items. That's not an argument for or against a ban. It's just the FDA was really thoughtful on how it did those.

DR. HEYMAN: The logo wear and the book bags.

MR. MYERS: The logo wear is already covered.

DR. HEYMAN: In the FDA Rule?

MR. MYERS: That's right.

DR. HEYMAN: But it just went the next step, and we toss it for the group's consideration.

REV. BROWN: And are you saying a ban without --

MALE VOICE: Mic.

REV. BROWN: The ban that you're talking about is without any exemptions. I mean, you're suggesting a ban without dealing with adult places or anything of that nature?

DR. HEYMAN: Right.

REV. BROWN: Just zero tolerance on all advertising and promotions?

DR. HEYMAN: Right.

REV. BROWN: Well, certainly we'd be in favor of that, and at the very least I think we have a PR problem as we talk about something like that. Not that it's necessarily that bad, but that we have to make sure that the ban is not perceived as an end all, be all for tobacco control and cessation activities.

Once it's no longer there, suddenly everybody is supposed to stop smoking, or kid are supposed to stop smoking, or whatever.

I think if we couch it right, I think it would be a good tool -- one of the tools we could use.

DR. KESSLER: Mike.

MR. PERTSCHUK: I was just going to raise a question which relates to Jesse's comment, whether it's useful or necessary to say to the extent permitted by the

Constitution.

We clearly have some. In fact, I think there's a good argument that it is constitutionally permissible or the court would find it that way, but it may be useful to just acknowledge that there may be constitutional restraints.

DR. HEYMAN: The group concerned itself because one of the things that was most encouraging about the Greensboro decision is that First Amendment issues were, in fact, not raised.

As I read this, and I certainly don't know enough about it, but I would certainly be concerned in reference to the so-called Central Hudson test, whether this, in fact, is excessively restrictive -- and Matt's nodding his head, so I think that's an issue which attorneys would have to look at, and it did concern the Committee this morning as we discussed this.

DR. KESSLER: Private parties certainly can consent to a ban on certain things if they wanted to.

DR. HEYMAN: Yes. Right.

DR. KESSLER: Dr. Graham.

DR. GRAHAM: I guess, David, as much a comment on process as the substance before us, although I'll come back to the substance.

I think as we do go through these papers and look at them seriatum but freestanding, we need to recognize that at some point all of these individual recommendations are going to be rolled into a position, a road map for what we think rational tobacco policy is.

DR. KESSLER: Right.

DR. GRAHAM: And we're going to have to look at the integrity and degree of compellingness of that document.

I have some concerns that, for us to be successful, in moving public opinion, a document will need to be prepared that the public finds to be credible and in their interest.

We can become perceived in the public's mind as too extreme.

DR. KESSLER: Yes.

DR. GRAHAM: Tobacco, we anticipate, will continue to be a legal product. Will the public find credible the advocacy that a legal product should be non-advertisable?

I have no objection to this as a freestanding policy at the present time, but when we put everything together, I think we're going to have to look carefully at the burden of rationality.

If we come across as blue noses, we're going to lose a significant part of public support, and if we have to compromise, if we feel that there may be, for legal reasons, or PR reasons, boundaries beyond which we don't go in terms of

marketing and promotion, I would be far more interested in linking marketing and promotion activities economically to the funding of educational activities.

In other words, sure. You can market as much as you want within these parameters but, dollar for dollar, everything you put into that marketing goes in in equal amount from your pockets to educational efforts.

So it's a process comment but also a substantive comment.

DR. KESSLER: But, Bob, assume that there are 50 or 75 other issues that are on the table. Where does that leave you on with one?

DR. GRAHAM: In isolation; comfort. And when we put that 20-page or 25-page document together and all of those 50 and 75 issues are together, I'll make that judgment at the time. Because I think it's very important that our document be compelling and something that the public looks at and says they have charted a path for us that makes sense.

DR. KESSLER: Do people basically agree with Mike Pertschuk's suggestion, of adding, consistent with the Constitution?

VOICES: Sure.

DR. KESSLER: Is there consensus on that?
VOICES: Yes.

MR. DAYNARD: Two things. First, a small procedural issue, is there some way we can move those lights? I sort of feel I'm at my eye doctor's and getting my retina examined. If there's some way they can be deflected. I don't know.

(Laughter)

MR. DAYNARD: I don't know how one appeals the heading of these lights, but they're really in our eyes all along here. Can anything be done about that?

VIDEOGRAPHER: Well, they haven't changed this morning's session. Your section is three stops below the other two sections. You have the least amount of light on you on that side.

MALE VOICE: So perhaps you better get your checks checked.

DR. KESSLER: Feel free. If anyone is sensitive there. I'm sure your colleagues at the other end will let you join them.

MR. DAYNARD: On the substance of thing, also on the question on the last point, which is how we address this, I think to begin with a notion that tobacco is a legal product, is a mistake. It's a mistake everybody makes. It's said so often it's become a cliche. It's a mistake.

I think, one, the history is that the FDA Statement of Jurisdiction basically demonstrates that this was a drug and a drug that was not registered.

No attempt was made to register this as a drug from as early as the early 1960s. That is, I think, the only fair reading of the Statement of

Jurisdiction.

So that this has essentially been an illegal product in terms of its history.

Secondly: If this ought not to be thought of as a legal product. It ought to be thought of as, essentially, in the same category as other kinds of illegal drugs, with one small exception.

The point as to why it should be thought of as an illegal drug is it's incredibly addictive, at least as addictive as any others; and much, much, much more deadly.

The only reason to make an exception on this is that there are 40 to 50 million Americans hooked on it, and as a matter of sensible social policy, nobody wants to try to cold turkey them.

But I think the proper way of thinking about this thing is that this is a product that, in all respects, ought to be illegal, but for the fact that it has established itself and established a beach head in terms of the number of people who are hooked.

So I don't want to continually be throwing in things, like consistent with First Amendment, and so forth, that suggest that the legitimacy of the point of view that this is really a legal product, it's really like every other product, and somehow we're just picking on it.

DR. HAFNER: I think my response is two part; one: Would I like the proposal, yes.

But, secondly, where Dr. Graham was talking a while ago about the doability and reasonableness of it as a policy, at that point, tends to overwhelm me in terms of a document that would be viable after it. So I'm struggling.

I'm wondering if, rather than talking about a total ban, if that could be addressed by asserting FDA control over all advertising. And if you go back, then, to how FDA controls advertising around other products, then it would leave us to convince the FDA that the banning advertising in that environment would be something we want and we'd be pushing for rather than stating it outright.

I'm on a limit, because I'd like to see it, but on the other hand, we've got millions of people we've got to get behind, and so that's my struggle.

DR. KESSLER: Other than the two points that were raised, and both important points, is there a consensus on it?

REV. BROWN: What's the consensus?

DR. KESSLER: You have a recommendation. There's two points, overall balance in the entire report, and the issue of whether you add in line with Constitution or you take Dick's point. Those are the two points that I've heard raised.

DR. WASSERMAN: Could I just suggest that maybe what we look at is extending. I agree with Dr. Graham, that we have to have a credible document. Maybe the area to extend would be to very liberally interpret restrictions against any area, any location where children might be at increased risk of being the one

marketed to, and then you're not a total ban on advertising, but you're focusing it and use some of the arguments that were used in the Baltimore lawsuit.

REV. BROWN: I think there's a problem here. The enemy, the other side, is going to characterize this as the first steps to prohibition, and I'm not sure how we navigate those kinds of waters if we publicly come out saying things like we support a total ban on all advertising and promotions.

I don't know how we do that and sell that.

DR. KESSLER: Why don't we see if there's other people who haven't talked.

Ms. Carol.

MS. CAROL: Jesse, with all due respect, the tobacco industry is going to accuse us of whatever we say as being the next step to prohibition. They always have, and they always will.

We've said it once, we've said it twice, we're not in favor of prohibition, and I don't think we should let that argument stop us.

Having said that, I would like some clarification as to what the introductory comments are going to be on the report because the subcommittees that I was on as well sort of had a difficulty figuring out, you know, on the one hand, we are public health community. If we don't ask for what really should happen, who will.

And, on the other hand, we would pick our times to ask for different things, and it may be possible that certain policies, for political reasons or because we haven't changed the culture enough, would not be implemented immediately.

So I think it would help all of us if we had an idea of what the timeframe around the blueprint is going to be.

Is this a blueprint saying, this is our vision for what ultimately needs to happen in public health regarding tobacco?

Or is this our blueprint for what Congress should get busy doing next year?

DR. KESSLER: Let me build on what you just said and throw out another option.

You have three potential options that have been advanced.

One is to prohibit all advertising;

To prohibit all advertising if it put children at risk;

Or prohibit all advertising that is consistent with the Constitution.

Those are three things that I've heard in the last 10 minutes.

What about Ms. Carol's point? What about some kind of tiered system?

If one is talking about a blueprint over the next 20, 30 years, and we are

talking about different incentives and different steps, does it make sense to have a series of steps, that would depend how successful one is at achieving the overall goal?

Matt.

MR. MYERS: Dr. Graham can have the first comment.

DR. GRAHAM: Just a quick comment on that is something that came up at lunch time is, again, going back to the full report, we think someplace else in the report there are going to be these incentives on the industry and maybe the states or maybe that's in the settlement, to step down the numbers of underage tobacco users.

Maybe one of the penalties for the failure to meet one of those thresholds is further restriction on advertising.

Start trying to link those things together, not just monetarily, but changing the marketing environment.

DR. KESSLER: Other points on the point Dr. Graham just made?

DR. HEYMAN: Perhaps the industry would come to the realization if they don't restrict their advertising and if the numbers don't go down in accordance with what's prescribed in this document, then they might themselves recognize that they need to trim their advertising back further.
It becomes a bit of behavioral modification self-imposed.

DR. KESSLER: John Beasley and then Mr. Myers.

MR. BEASLEY: I think we over estimate how concerned the public would be over the issue of restricting advertising tobacco products. I don't think that that's something that -- if you're talking about a report that's going to have a mass appeal that it's going to outrage most of the readership of that.

I do agree that it would be an issue that might generate concern in Congress and certainly with publishers and advertisers.

But I don't think there's a great sympathy in the public for -- they don't care if there's cigarette advertising out there or not.

DR. KOOP: I think it's important to remember that the last USA Today poll, which was about two weeks ago, that more than half of Americans said that a legal product, tobacco, should be free to be advertised by the industry as they saw fit.

DR. KESSLER: I think Matt and then Bill.

MR. MYERS: I think that point you made, and actually the approach that's implicit in the FDA Rule itself is one that makes sense.

Our goal is to reduce the number of kids who start. Our long-term goal is to reduce the number of adults who die.

We've set ourselves on a course, theoretically, through your original recommendation, to eliminate those forms of advertising that have the greatest impact on children, in an effort to achieve the first goal.

I think Dr. Graham's approach is one that makes sense, although I would expand it, which is to say that we ought to evaluate how we're doing in terms of our public health goals. And then if additional action is needed, in order to achieve those goals, both goals, I would say, then additional restrictions on advertising designed to achieve those goals ought to be in our armament at that time.

That way, you're more likely to withstand a First Amendment challenge because it's directly tied to a legitimate public interest.

We've tried the lesser included step that we're doing right now, to give it an opportunity, and the public health need to reduce the death toll from tobacco will only grow over time.

DR. KESSLER: Bill.

MR. NOVELLI: The various options that you just laid out all seem good ones to consider.

I would simply add that I think this is a really profound question right now. Even though we're talking about advertising and marketing, each one of the areas that we get into, it's going to be tempting to go the full measure.

As we discussed at the last meeting, and as I think we set as a criterion for ourselves, we need goals that are achievable and that where realistic.

I would fear that if we develop a document that talks about banning advertising and talks about other measures that the public, the Congress will consider to be extreme, it doesn't matter what the tobacco industry tries to hit us with, we will essentially end up with a shelf document and not a document that will be considered a real road map for change. DR. McCAFFREE: I sat on this Committee, and some of these issues we did discuss. But the Committee felt one of its charges was, in fact, to develop proper, reasonable, and achievable public health goals for a blueprint for public health policy.

We felt that this, in fact, was reasonable, proper, and achievable.

There is, in fact, no reason to advertise an addictive and deadly product. And, therefore, we thought that we could make this case to the public, and I agree that I think we may be overestimating the public's reaction to the ban. DR. KESSLER: Dick and then Mike.

MR. DAYNARD: I just want to point out, before we decide that this is pie in the sky, that two countries not known for the repressive natures of their laws, Canada and Great Britain, have recently gone the route of complete bans on advertising.

And particularly if we're talking about a document that's supposed to be not simply what we want right now but what we see over the next 20 years, or whatever our charter is, not to put in here that we want a complete ban on advertising and promotion for exactly the reason that Dr. McCaffree just pointed

out, I think would be wrong on our part.

DR. KESSLER: Mike.

MR. PERTSCHUK: Well, actually, a larger point, but I would point out to Dick that Canada did pass a ban and ran into problems with their Supreme Court.

MR. DAYNARD: They just passed it again.

MR. PERTSCHUK: But they haven't been through the Supreme Court again.

I wanted to pick up on Julia's point, because I don't think we'll ever get to a discussion of Task Force Five.

DR. KESSLER: We will.

(Laughter)

MR. PERTSCHUK: But to respond to your comment and the general thought that we need to set some long-term goals and some interim steps.

We struggled in our task force with the international recommendations. Clearly, some of them are not attainable even by a democratic congress without any tobacco lobby, in the short term, some of them are very much attainable.

So I would like to see some effort made to have us set the long-term goals and to identify them as long-term goals, and I would agree that a ban on all advertising is part of that, but also identify some of those that are short-term steps as a means of presentation.

DR. KESSLER: Let me take one or two more comments.

Jonathan.

DR. FIELDING: One way to think about this is if youth is our primary concern, we could say, I think, with good evidence, that the advertising to kids is not only through and promotion of marketing to kids, is not only through the vehicles that the industry agrees that are to kids.

So when we say we're trying to ban everything to kids, we know that stuff is likely to get through to kids.

One of the things to do is say we should start with the ban on things that are directly to kids but to support strong research of the continued marketing promotion, advertising to adults.

If, in fact, it appears that that's having a major impact, continues to have a major impact on kids, then additional measures such as a complete ban should be considered as consistent with that first objective.

DR. KESSLER: Why don't we, to be helpful to, just as sort of a straw poll so we can move on and we can try to get to Task Force Five, it sounds like there's three potential things talked about, and obviously versions of those; a total ban focused on kids and then a phased approach.

Are those three different approaches that I've heard? Is that a fair characterization? I don't want to leave any out.

It would be helpful to the Subcommittee and not something that you can't take back, and you can vote more than once, so we can relieve angst.

Let's do a show of hands for the Subcommittee so you have sense of where the total committee would come out.

Let's start with a total ban, the report as written. Who thinks that the report should stay like that?

(Show of hands.) DR. HEYMAN: I've got that. Thank you.

DR. KESSLER: The approach on focusing on advertising to children and when children are at risk in banning it, in those contexts.

(Show of hands.) DR. KESSLER: Do you have that? DR. HEYMAN: Yes.

DR. KESSLER: And then a phased approach that perhaps starts with one and leads to the next. Can we just see a show of hands on that?

(Show of hands.) DR. KESSLER: Is that helpful?

MR. NESBIT: Who won?
DR. KOOP: I'd like to make the point again, which I've tried to make before, to remind us what we're doing.

We're writing, at the request of Congress, a blueprint that they can use as the standard against which to compare other suggested ideas, such as a settlement.

It seems to me with the proper page or page and a half Preamble of what we're doing and why we're here, that we can set out for them an ideal and say how Congress chooses to reach this ideal is up to Congress, but this, in the best of all worlds, would be the way we would see it.

I think that you have to remember that a lot of the things that people are objecting to around this table have already been agreed to by the tobacco industry in their settlement, if I understood what Matt Myers said today.

And this raises another issue, and it's process now and not substance.

We accepted this thing, and we said in the beginning, at the request of Congress, we would get a quick turn around, and we suggested we do it in 30 days.

This is our second meeting and it is now the 18th of the month. Both David and I have problems in the immediate future, he assuming the deanship of a University Medical School and I with some surgery, and the American Medical Association meets next week, and getting us all together is going to be a very difficult time.

Could I ask how many people could be here for a half a day next Monday?

(Show of hands.)

DR. KOOP: That's not really a great many people. One of the things that we could do is to do a lot of this by mail rather than to postpone the deadline until the middle of the summer.

Does anybody have any suggestions about process about this that might be germane?

DR. HEYMAN: I think, personally, it would be very helpful, for example, if everyone were to take a clean copy of this and mark it up and make their suggestions on it, and if everybody could commit, for example, to mailing this back to the chairmen of each of the individual task forces, that chairman then to work with his or her staff person to refine the document and perhaps get a second draft to you as soon as a week to 10 days, is a process which I think might work for us.

DR. KOOP: Do we have consensus on that? Does that meet with everyone's approval?

DR. BANZHAF: E-mail as an alternative?

DR. KOOP: Yes.

DR. BANZHAF: So we can mark it up directly?

DR. KOOP: I beg your pardon?

DR. BANZHAF: E-mail as an alternative so we can mark it up directly?

DR. HEYMAN: For some of us who are like technologically impaired it's a little cumbersome.

(Laughter)

DR. KOOP: Could I suggest that instead of sending it back to the chairs of each committee we pass it through our staff here and then to you?

DR. HEYMAN: Fine.

DR. KESSLER: That would make it easier for you in the long run.

DR. FIELDING: I just have a process question, Dr. Koop, and that is, we have reports now, subcommittee reports, that differ tremendously in tone, in length, in the way they're ordered and recommendations, and I'm wondering who, what process is going to be used.

You know, let's say we had agreement on each of these four, in getting them altogether into one document, and then reviewing that?

DR. KOOP: A very small voluntary staff has already committed itself to harmonize these things and even to go further than that, and I'm not going to

tell you how far because I don't want to disappoint you.

DR. KESSLER: What's the one or two other issues that you think require discussion of this committee in this report? Let's do it that way.

DR. HEYMAN: Dr. Kessler, if I could just suggest, I think the way that, at least this particular report is organized, would really lend itself nicely to each individual member of the Committee, reviewing it and sending back comments, and I guess what my concern is, if I highlight one or two issues as being my chief agenda, I'm afraid I'll belittle the other aspects of the report, which I think are important.

DR. KESSLER: If you look at the big issues here, we do want to get on the record some of the discussion. I think the discussion on advertising, even though it was just 20 minutes, dealing with something that large was helpful. So things of that kind of magnitude.

Dr. Banzhaf.

DR. BANZHAF: Yes. I was going to suggest generally on advertising and the other issues that we may be making the mistake we've been making for the last 20 or 30 years, and that is being far too timid and behind the public in terms of making recommendations.

People are going to say if a group of health people are not willing to recommend X, and certainly that is not something which is world doing.

Many people here say we should ban advertising. This is not anything radical. It's been done in other countries.

If I remember correctly -- and, Tom, you can correct me if I'm wrong -- the AMA recommended it a number of years ago. They're hardly thought of as a radical, militant organization. They recommended it. The Congressional Research Service has issued an opinion, saying that it would be constitutional.

But I go back and remember --

DR. KESSLER: Let me just --

DR. BANZHAF: Okay.

DR. KESSLER: I am committed to getting to Task Force Five.

(Laughter)

DR. KESSLER: I'm sorry. No one may talk to me after it, and it may not be the most satisfactory process, but we have until five o'clock, and we're on Task Force One.

Other major issues that people would like to discuss?

John, we've discussed one. If there's another one, please put it on the table.

Ms. McGrath.

MS. McGRATH: Mine is a process issue.

Since our consensus seems a bit shaky, what I would suggest is that we make comments in writing and then have a final conference call before the report becomes public to see that we really do have a consensus.

DR. KESSLER: Jonathan.

DR. FIELDING: On major issues, I guess, looking through this, I think a major counter-advertising effort, that's on page three, the first policy recommendation, that's another big piece, and it would be important to have consensus on.

DR. HEYMAN: Our Committee, at least, didn't consider it especially controversial.

DR. FIELDING: I just think that it is an important recommendation, one that the public is likely to pay attention to, and I just think it's important to make sure there is consensus on this issue.

DR. KESSLER: Anyone like to comment?

(No response.)

It sounds like there probably is.

One or two others issues that people would like to address here in this task force report?

MR. NESBIT: Can I ask a question?

DR. KESSLER: Sure.

MR. NESBIT: This morning, from Christine Gregoire, we heard the discussion about the penalties, that they all meet the targets.

Where in this document do we sort of parallel or deal with that kind of an issue?

DR. HEYMAN: On page 7, bullet number 7.

MR. NESBIT: So it tracks with what's in the --

DR. HEYMAN: It talks about the industry should be subject to penalties and talks about giving the industry incentives, limit the potential liability for failing to reach the targets.

This is where, if the group had gone that way, this would be an ideal place to fold in increasingly stringent regulation of advertising, and then of course the plain packaging provision as well.

MR. NESBIT: Because we had such a lengthy discussion about that this morning, I guess I would ask folks around the table what they think of your recommendations that's in this document.

MR. PERTSCHUK: Just a point of order.

DR. KESSLER: Yes, sir.

MR. PERTSCHUK: And I agree with Jeff. Could we also consider the criteria for the performance-based penalties, which are offered at page 15 of our report, at the same time?

DR. KOOP: If Dr. Koop will allow, perhaps what we do is maybe we can have one discussion of the performance-based standards, and all Committees can -- we can take 10 minutes to just look at performance-based standards, whenever you're ready to do that.

Before we do performance-based standards and do Jeff's question, let me just give you another minute to go through this and see if there are any other issues besides performance-based standards.

MS. SOPENSKI: The only other question I had and that we didn't get a chance -- sorry -- the question I had that we didn't get a chance to talk about in our Committee was environmental tobacco smoke and children.

I would like to at least charge the Committee with addressing that issue, specifically. We addressed it on a research basis but we did not address it in any practical way about how it would impact children's lives as part of our policy.

DR. KESSLER: Any other issues on this report?

Ms. Carol. MS. CAROL: Just to clarify and to add-on to what Judy is saying, because I'm not sure everybody understands it as well as some of us do.

Many of us have a strong belief that working on the secondhand smoke policies are actually good prevention strategies for youth. They're not seeing smoking role-modeled.

And that we want to see more of working on the demand side of the youth issue to balance the strength of the access side.

DR. KESSLER: Tom.

DR. HOUSTON: As a member of the Subcommittee, I'd like to second what Ms. Sopenski and Ms. Carol have just said, and we certainly support that at the AMA.

The other piece that got up briefly at our Subcommittee meeting this morning was the end to increase excise taxes or, in whatever other method, radically increase the price of tobacco products, given that for a lot of economists who think about this -- Ken Warner and others -- would say that dramatically raising the prices a la Canada would be almost the single-most effective thing one could do to prevent uptake by youth and increase cessation and give incentives for youths and adults, as well, to stop smoking so that this is another piece, not only for smoking cessation but for youth that need to be brought up.

DR. KESSLER: Let's talk for one minute on that, on excise taxes.

Are there any other Committee reports that deal with excise taxes? No? So this is a good time to do that. We'll just spend, literally, two, three minutes, just to make sure that we can crystallize our thinking on that.

Dick.

MR. DAYNARD: Yes. I think we can be open about whether it's excise taxes or another mechanism, such as required payments from manufacturers, perhaps on a per-pack basis, perhaps on another basis, that produces the same result.

But I would think that we could certainly come out, or we should come out, with a goal of raising the price of cigarettes as quickly as possible by at least $2 a pack in 1997 dollars, that being a doable amount in terms of revenue maximizing. That's my little piece that I had sent out, and Jeff Harris' piece.

It's the amount that had been asked for by Cancer Society, I think the whole Coalition several years ago.

And nothing has happened since then to make that any less appropriate a goal, and it's something that I think could be expected to produce at least a 50 percent drop in consumption among kids.

Whereas, all of the other techniques that we've heard about directed at consumption among kids, I think have much less empirical evidence behind them.

DR. KESSLER: Reasonableness of the recommendation like that? You were much more general in your recommendations. Does anyone care to?
Mike?

MR. PERTSCHUK: I would support it, but I also would want to observe that these price increases should come from excise taxes, both at the federal and state levels, that they are both areas, since there's a good deal of energy at the state level, to encourage that as well.

DR. HEYMAN: It'll also be critical to mandate that the tobacco companies not then drop the price of their product so that there's no net increase in the price at the marketplace.

DR. KESSLER: Dr. Wasserman.

DR. WASSERMAN: Just the reasonableness of this. I believe that, in Maryland, when we went over the figures, the cost, the net costs directly and indirectly associated with health costs of tobacco is about $3.65 a pack, so a $2 increase in taxes doesn't even offset the current health care costs.

So I think it's a legitimate amount of money to put on the table.

DR. KESSLER: Anyone want to play Devil's Advocate on that?

Julia.

MS. CAROL: Actually, I favor the tax, but I've always thought it should be a percentage of the price, the way that sales tax and other taxes are, so that if the price goes up the amount of tax revenue goes up. You know, I've just always

thought that was a better way of doing it.

We could figure it out so that, right now, it would equal between $2 and $5 a pack.

DR. KESSLER: Anyone who hasn't talked?

REV. BROWN: One of the issues of raising those, how ever we raise the revenue, is that it's generally on the backs of poor folks.

And the whole regressivity issue, I would suggest that somehow we also make certain that those very same communities or people receive some of those dollars back so that we could accept a notion that it was regressive.

DR. KESSLER: Mr. Beasley.

MR. BEASLEY: I was just going to say, on the percentage, if you set your taxes a percentage of the price, you have the problem, which we saw when we raised our tax, when we talked about this, of these discount brands, so that you're collecting less tax on the lower-priced cigarettes, and when the price goes up, smokers will shift to the lower-priced options.

So you have a less as an effect --

MS. CAROL: But children like the brand.

MR. BEASLEY: That's true. Children do. Yes.

MS. CAROL: Children are buying Marlboros and the expensive ones.

DR. KESSLER: Anyone want to try to crystallize our thinking on taxes, what you just heard?

DR. FIELDING: One minor suggestion. That is, it's been suggested in other documents that this be indexed, at least to the CPI, or something else, because that's been a big problem all along. You know, it says at this level for 20 years, as prices double or triple.

Not the price of cigarettes but general prices in a market basket. So I think the notion of indexing should be included.

DR. KESSLER: Anyone else want to try to crystallize thinking on the tax question?

DR. KOOP: I think you ought to start off the way Dick did, that every single tobacco economic study that's ever been done that's credible has shown what he said to be true, that you can cut cigarette smoking about in half if you do it properly.

And then you could do what he said, choose the amount of money, at an increase of $2 per pack in '97 dollars, which would increase according to inflation or the price of the cigarette product.

Then tailed to two different things, and they move upward and couldn't move

downward.

I think it should apply to generic brands of unlabeled cigarettes, as well as the popular brands.

DR. WASSERMAN: Is that a suggestion of like a $2 additional tax now and it index from there?

DR. KOOP: Yes.

DR. WASSERMAN: It sounds good to me.

DR. FIELDING: I assume the procedural question is this covers all tobacco products, not just those that are smoked, not just cigarette packs, or am I wrong?

DR. WASSERMAN: Right.

DR. FIELDING: Okay.

MR. BEASLEY: How do you do it on cigars?

DR. KESSLER: The price of cigars these days that's a lot of money.

DR. KESSLER: Mike, would you be kind enough to join us and, Dr. Heyman, why don't you stay? That way we can go to the --

STAFF: Where did we end up on the ban? We took a vote on three suggestions. Where did we end up?

DR. KESSLER: I think you have a pretty good sense of where people are.

DR. HEYMAN: I tabulated the numbers, and we'll keep them quiet so that I can make my own decision.

(Laughter)

DR. KESSLER: I think everybody had a pretty good sense.

I made a commitment to get to Task Force 5, so let's go from 1 to 5.

(Laughter)

INCENTIVES

DR. KESSLER: I'm just kidding.

Please, and your colleagues please feel free. But let's go to the incentives, and let's discuss that.

If you could just articulate in both 1 and 5, where do we stand now? What should we call this, incentives, performance standards, penalties?

MR. PERTSCHUK: You've got performance-based monetary penalties.

DR. KESSLER: So be it. Do you want to just summarize, Mike?

MR. PERTSCHUK: I will. It's on page 15 of our report, but I should say that this language was offered, Jonathan, by Judd, and so perhaps Jonathan should really address this. Or is Judd here? We should get credit where credit is due. This was your language, and suggest Judd if you want to.

DR. KESSLER: Please feel free to come to the microphone.

MR. PERTSCHUK: Yes. The discussion of the task force, and -- actually, Judd had a memorandum to us as we prepared it, pointed out that there are enormously complex issues involved, just as we discovered this morning through the questioning and, therefore, recommended that rather than this task force recommend a formula or a sum, that we develop a process, and the process is the process that's described here, that the penalties be set through an FDA rulemaking proceeding, which draws upon the kind of data needed to test any performance-based standard against the criteria which is suggested here.

I think that's really the basis for the recommendation.

DR. KESSLER: What guidance would you give the Agency?

MR. PERTSCHUK: Well, these are the incentives. Incentives are, obviously, the question. What kind of incentives really are meaningful incentives.

A second is to --

DR. KOOP: Economically punishing incentive.

MR. MORRISON: I would put it in terms of -- I'm trying to write the statute, but it would be a statute which would direct the agency to create incentives that substantially reduce the percentage of smokers by -- either youth smokers or all smokers -- by, and Congress could set a goal and give it the discretion over what period of time and in what amounts and the penalty sufficient to achieve that.

I think we could write a statute, not here today, but we could do one that would pass constitutional muster in terms of the adequacy of direction to the agency.

DR. KOOP: But it has to include provisos so that the cigarette manufacturer couldn't, by the simple expedient of raising the price of cigarettes, wipe out the cost to him of what the incentive was supposed to be.

MR. MORRISON: Well, I don't know that that's necessarily the case. It may be that you have to decide whether the goal is to reduce smoking, and if the manufacturer can pass it on to somebody else, and then it's going to cause some other kind of harm, then you've got to deal with that other kind of harm.

Or whether the purpose of it is to raise revenue, in which case then you're doing another set of activities.

My understanding was that the purpose of this is to be sure that the promises that are being made to reduce smoking will, in fact, be materialized, and that's the way we've tried to design the structure, but there may be two conflicting

goals here.

DR. KOOP: Well, I think that that's right. That's what the goal is. But if it comes out to a punishment of 6 cents per pack of cigarettes sold, that's not an incentive.

You could ignore it, do all you wanted to to promote cigarettes --

MR. MORRISON: Oh, yes. I understand what you mean. I didn't understand what you meant.

Obviously, the incentive has to be of sufficient magnitude to achieve the goals.

DR. KOOP: That's why I say economically punishing.

DR. KESSLER: Could we discuss that just for a second? Matt and I, as we discussed this morning, Matt's words were you can't trust; you're going to change corporate behavior by these tools.

What is it going to take? You can leave it up to an agency to assess what it's going to take, but if you had to give some kind of recommendation, what is it going to take if this is one of the key tools?

And I'm not sure I see a lot of other tools to really change incentives. There may be others, but this is one of the big ones. What is it going to take to do that?

MR. PERTSCHUK: There's a middle ground between our setting what that penalty should be and leaving it up to an agency.

I think what Judd was suggesting and what we've been working at is what kind of guidance do you give to the Agency in terms of its process, which clearly has to specify, first of all, an extensive amount of fact finding.

I mean, what we really do not know is what are incentives, and that involves some rather extensive investigations of marketing practices and judgments from those in the marketing business, but with the criteria being the one that Dr. Koop suggested, that the goal be to establish a level of penalties which really work and in which the decision-making process of the companies is such that it is affected by the level of penalties which are opposed.

That really was the thrust of the discussion this morning, that the penalties clearly are not designed to do that.

I mean, I think what I heard Matt say is that these were really designed as an add-on penalty, that in addition to all of the other monetary penalties which would be imposed or the amounts to be paid out by the industry, that this was an additional incremental set of penalties which would be motivating, and we don't know that.

I mean, we just don't know that, and I don't think we can answer it. But we can use the kind of language that Judd has suggested to suggest a series of criteria to determine what those penalties are.

First of all, the principle can be established in the report of the purpose of these penalties and then a process and then some criteria. That's the best you can do, I think.

DR. KESSLER: Comments. Dr. Wasserman?

DR. WASSERMAN: Just another way of looking at this, in trying ultimately to reduce consumption, has anybody thought about limiting the amount of billions of packs that could be manufactured over that point in time, so that if you could go down to 10 billion packs manufactured what would be the pros and cons? That's a different way of looking at it.

MR. MORRISON: That's a form of prohibition. You've created a Black Market for it, and it may be that that's how one would measure it in terms of the number of packs made, as to whether they've met their goals, but in terms of doing it, it seems to me all you're doing is creating a Black Market, and that's undesirable for reasons that others have spoken.

I would say one other thing about this: This is intended to be a fallback if the other primary regulatory objectives don't work.

I believe that's right. That is to say, if the youth access things work as everybody hopes they will work, then maybe you won't need this, but to the extent that it's not, then of course it's got to do more than that.

DR. KESSLER: Can I take exception?
MR. MORRISON: Certainly.

DR. KESSLER: I just think there's always room, no matter how you write any provision, to either comply with the spirit and want to comply with the spirit or to game it.

I think one of the key things that's critical is making sure that the industry has the incentives, against its better interest; that's what hard here. We're asking them to reduce the number of people who will smoke. It's not something that that industry becomes naturally or you can expect to come naturally.

That's why the incentives are absolutely critical and must really, I think, take a prominent role in any kind of national policy.

I think you can argue that the incentives are as key, not necessarily more key than the other provisions, but they're as key as the other provisions.

Let's continue. Dick.

MR. DAYNARD: Yes, a couple of things.

I'm a little worried about giving the FDA broad rulemaking, rule design, setting limits, setting levels, and so forth, authority.

You're asking an agency with a thin political base and, indeed, not even independent of whatever administration is around, even formally, to make multi-billion dollar decisions.

And I would think, to the extent we can articulate the appropriate criteria, we ought to do it. I could well imagine the FDA letting itself, or not letting itself, but getting bound up in administrative red tape, appeals, whatever, and not being able to come out with anything on this.

I think it's better, indeed, if we could do it by statute, if we could have something that was almost right and got it in solidly with the FDA having a chance to fix it, rather than leaving it for the FDA to come up and for some court of appeals to decide that they had proceeded along properly.

Then I think in terms of details, one way to keep the industry, to make this more effective, I think, would be to do it company by company and have each company's products rather than the industry's products as a whole. After all, economically, in terms of economic incentives, that's the way it works.

Well, the industry stands opposite us and a monolith in terms of their profit maximization; they're a seres of separate companies.

If we did it in terms of the products of the company, I understand there's some problem of getting accurate baseline on that, but that could be solved by doing a study in couching the thing.

That would also keep the companies from just passing it on in the price. You pass it on in the price because you've been hit. Because Marlboro is the biggest seller, so you've raised Marlboro. Camel isn't up because Camel played it straight and it starts running the -- and there are all kind of things they can do. David Kessler is right. All kind of things they can do.

They want to depress the market, they can just, instead of running the Camel ads, they can run these wonderful cartoons that say -- the camel is in a doctor's office, an x-ray up there. And the doctor says, I'm sorry to tell you but you have cancer of the hump.

They don't need to do very much of that stuff, I think, to demarket this. If they want to demarket, they can figure out how to demarket. If you do it by companies, then they're not going to be able to raise the price, because if one demarkets and the other continues to market the product to kids, they are going to have to raise the price above their competitors. That's not going to work in the marketplace.

DR. KESSLER: Mike, do you want to respond?

MR. PERTSCHUK: I have three points.

One is, it seems to me that you ought to establish a small working group to work with the staff to seek out from the rest a set of criteria that would be as tight as possible to govern FDA.

The second point is that --

DR. KESSLER: Is there any reason why your group can't continue to do that?

MR. PERTSCHUK: Well, I'm not sure we have the expertise. I think there may

be some others --

DR. KESSLER: Why don't we just ask you to add that expertise?

MR. PERTSCHUK: Well, we can certainly try and do that. We can certainly try and do that.

The second point is really, also goes to Dick's concern about FDA and really leads us into a second major issue for the task force, which is Alan's paper on Litigation and the Importance of Litigation.

Because, in that, as important as the litigation that we talked about otherwise, that is, the class actions and the rest, is the ability of citizens to challenge the agencies to carry through their missions.

This really goes to importance of providing for citizen access to challenge FDA in the future to enforce its regulations, which is another safeguard against the FDA not doing its work.

The third is a question. I am puzzled, I'm confused about an issue that's been raised, which is Dr. Koop's concern and others, that we not let the companies pass the cost on to the customers and our desire to raise the price of cigarettes to dissuade kids from smoking.

(Laughter)

So I'm not sure if we're not talking at cross purposes, and I don't quite understand it.

DR. KESSLER: John and --

MR. MORRISON: Dr. Kessler, could I add one thing?

DR. KESSLER: Sure.

MR. MORRISON: Dick has masterfully put his point on the two polar opposites that we're driving our concern.

On the one hand, he doesn't want the FDA to get it because it's going to be too complicated and too delayed.

On the second hand he says, well, we have to go on a brand by brand basis, which is going to require us to have a study in order to set baselines.

It seems to me we can't do both things, and I don't know what the right answer is.

My concern is that neither we nor the Congress, and if you talk about worrying about putting something before the Congress where a small little slip in the data can change the entire incentive system, I'm not so sure putting it before Congress, where it would have to go in any event, in the first instance, would do any good either.

I'm not sure you're wrong, but I'm very concerned about getting the right way to do it.

DR. KESSLER: In Dr. Koop's words, crisp and short, crisp and few.

DR. BANZHAF: Every time I come up, it's crisp and short.

(Laughter)

I strongly agree with this --

DR. KOOP: There might be a message there.

DR. BANZHAF: Yes. I've been talking less than a lot of other people around the table, who haven't been cut off.

I strongly support Dick's idea that there be individual responsibility. While I like the idea of setting out all of these elaborate processes. As we know what we produce here today, is going to be compared with the settlement.

If such a settlement comes out, they have numbers. It seems to me, we've got to come up with numbers. We can't have a process.

Their number, again, is $80 million, 4 percent. That's about 1/1000th of their profit.

Now, just five minutes ago, we were perfectly willing to say we wanted to have a $2 increase on cigarette taxes. It seems to me we can come up with a better figure. Indeed, there's a very simple, good place to look.

By the way, when you want to modify behavior, you don't do a cost-benefit analysis.

When any of us wanted to get our kids not to do something, we didn't try to figure out how much benefit they got out of riding their bike across the street, and balance that against an hour or two hours of television; you come up with a big penalty, then they don't do it.

We have a bill which has been introduced by our colleagues on the Hill; Congressman Waxman and others, which provides much more ambitious goals and much stronger penalties.

And I absolutely guarantee you that if this committee comes out with something substantially weaker than that, that is going to be used against them on the Hill. "Waxman says we ought to have this; oh, this blue ribbon committee says about a third of that will do."

I don't think we ought to undercut our folks up on the Hill.

Let's start with their bill, work with their bill if that is inadequate; then maybe we can discuss it, but the penalties in the settlement seems to be less, and what's being kicked around here is mostly a lot of language.

We can come up with numbers; those numbers exist in the bill.

DR. KESSLER: Dr. Anderson.

DR. ANDERSON: Strong support for performance-based incentives and penalties. I have a caution, though, from what I've heard; and that is that although avoiding a penalty may be viewed as an incentive, normally incentives are positive things.

And I think we need to focus very closely on that when you put the language together.

I would look at incentives as coming in the execution of programs that result from what we recommend.

I think you're really talking primarily about penalties, though; and to communicate that as an incentive to the tobacco industry may be just plain wrong, in terms of the way we're setting ourselves out.

So I would caution you on the difference between penalties and incentives, as we communicate this.

DR. KESSLER: Let's go back to Mr. Banzhaf's point for a second.

Any thought of how to handle that? There certainly was discussion this morning of what the penalty or incentive, or what you call it was really very meaningful, as being discussed.

How do we address John's point?

MR. MORRISON: Well, I suppose part of the question is we'll have to go talk to Congressman Waxman's staff and see what kind of data they've got on it.

That is, the concern I have is that even that system, just because it's a large number -- we could put a billion dollars for every percentage point, and that would be certainly strong enough.

The question is, is it rational and is it fair? And we want to follow what Dr. Kessler said, which is we have to appear reasonable.

And until we've looked at those studies and had people critical of them look at it, it's hard for us to make a judgment; which is one of the reasons I personally preferred not trying to make the judgment now, because I think these are quite complicated matters; but we certainly can do that.

DR. KOOP: I think as guidelines, you might remember what John has said and what Waxman's bills.

His calculation is that the present so-called penalty is 6 cents per pack.

He's suggesting $2.00. Now, that is a real economic punishment which I was talking about, and I agree with that.

MR. PERTSCHUK: I think we need some guidance.

We can pursue whichever course the committee wants, but there are different --

DR. KESSLER: How would you ask the question, Mike, of the committee right

now?

MR. PERTSCHUK: Well, it seems to me there are two essential proposals on the table.

One is that we try and develop a series of tight criteria, and the process for FDA to develop penalties, which will work as penalties.

And the other is that we develop a consensus on a specific level of penalty based upon, at least as a starting point, based upon what Congressman Waxman has proposed in his legislation.

DR. KESSLER: Mike, is there a third alternative?

MR. PERTSCHUK: There always is.

DR. KESSLER: Well, is there a third alternative that leaves the definitive -- based on the analysis, but some kind of ballpark order of magnitude that --

MR. PERTSCHUK: Yes, including a range. I mean, there might be a range of penalties in the report with directions to FDA to move within that range.

DR. KESSLER: Comments on those three different kind of strategies.

DR. FIELDING: I think it's going to be very hard for us today to agree on what a particular range would be; I think a small group could probably go off and get some additional expertise and try and do that.

So I think we should focus on what are the key criteria, and I have a couple of suggestions for that; and that is to say the penalty should exceed the profit from each additional pack, whatever it is, unit sold.

That's really the principle that I think Dr. Koop was talking about in terms of strong economic penalties, that in fact it's going to cost them for every additional tobacco product sold, if one does not meet -- does not meet the performance goals.

But secondly, I think they should be graduated; and that suggests again, in Congressman Waxman's bill that -- and you know it might be graduated in two ways; number one for how long in fact the performance goal is not met; and two, how far from the target one is.

One can say, you know, if you're within five percent it's this per pack; if you're five to ten percent off, it's that.

So I think some graduated way makes sense as an overall approach.

And I want to second what Mike said about raising the price.

It may be that we will cause prices to be raised from that, and they may in fact make more money in the short term.

But if we are reducing the base of smokers eventually, we're basically achieving our objectives.

DR. KESSLER: If I understand Matt this morning, he said that the methodology that he had used was based on eliminating the profit from each additional child who smokes.

Matt's not here, and -- that's what I heard him say.

DR. KOOP: That' what Waxman figured out to be 6 cents per pack.

DR. KESSLER: Any thoughts of whether there's other --

DR. FIELDING: Six cents a pack? The bill says that there's a dollar --

DR. KESSLER: No, no no. That's in the current settlement.

DR. FIELDING: Oh, I see; I'm sorry.

DR. KESSLER: Let's just go around one last time on this question. What would be helpful to you as you write the next --

MR. PERTSCHUK: I think what would be most helpful is a direction and a show of hands on whether we should try and do what Waxman did, which was to find a number or a range of numbers.

And secondly, whether we should couple that with criteria for FDA to adjust.

Or third, just have the criteria.

So there are really three different proposals before us.

DR. KESSLER: Restate them, Mike, so that everyone understands very clearly --

MR. PERTSCHUK: First, what we propose -- and actually, I'm making an assumption which I will repeat.

Which is, I gather there is a consensus that penalties based solely on the loss of profits gained from the sale of those cigarettes to children are not deemed sufficient by the committee.

Therefore the challenge is to find a means of developing penalties which are really meaningful in affecting behavior.

There are three possible ways of doing that.

One is to develop a process -- as we've recommended -- a process and criteria for FDA to apply, period, without mentioning any numbers.

A second is for us to set a number; that is, to take for example the Waxman bill and incorporate its numbers into the report; and the third is a combination, which is to identify a range of numbers, the possible range of numbers; but those numbers to be acted upon by FDA after a full rulemaking procedure and further fact-gathering.

DR. KESSLER: Is there really -- when you give people the -- are there really just two here? There's process and criteria versus a range of numbers meaning

criteria.

Is that ==

MR. PERTSCHUK: Sure, that would be helpful.

DR. KESSLER: Is that a --

MR. PERTSCHUK: It's really one without numbers and one with numbers.

DR. KESSLER: Right.

MR. BANZHAF: Can I concisely suggest a fourth?

DR. KESSLER: Sure.

MR. BANZHAF: Can we do what we did with tax; that is, come up with a number initially and then say it may be adjusted in the future by the FDA based upon various criteria.

MR. PERTSCHUK: That is what we understand to be one of the alternatives.

MR. BANZHAF: So if we start with the Waxman bill and then say "If it doesn't work, FDA can increase it but not decrease it." The same as we did with the tax.

DR. KESSLER: Leave aside some of the -- the important points, but let's just go to the question of some range of numbers versus --
MR. PERTSCHUK: No numbers.

DR. KESSLER: No numbers.

Can we ask for show of hands? Perhaps you can vote on each one of these, but then that would be a little contradictory --

(Laughter)

DR. KESSLER: That shouldn't stop you. I don't want anyone to feel --

All those in favor of having some range of numbers or sense of numbers along with criteria and other conditions, why don't you -- if you'd be kind enough to show your hands.

[Show of hands]

DR. KESSLER: Those who would be opposed to having any range of numbers in here?

[No response.]

MR. MORRISON: That's helpful.

(Laughter)

MR. MORRISON: Somebody has to give us the numbers now, but that's a separate

problem.

DR. KESSLER: It's a range of numbers.

MR. HAFNER: I think the whole crux of this discussion has gone on somewhere else in the city, is tied right to this.

DR. KESSLER: Do you want to say more?

MR. HAFNER: Only from standpoint that I think numbers are to be offered and they ought to be clearly numbers that are a disincentive, that they are a penalty; they're not an incentive, they are a penalty.

And I think that is core to all the discussions that are going on elsewhere. I don't see how we cannot --

DR. KESSLER: Are you saying current numbers that are being thrown around currently tell you, give you some sense of what the current market bears; and you may want to work from that.

MR. DAYNARD: Can I make a suggestion? Which is, in federal law where there's something that you want to discourage, even in civil law there's something that you say "If you do this, this is a bad thing and we want to discourage it" there is a standard measure, and the measure is triple damages.

And maybe that would be a good place to start, to try to figure out what the benefit would be, which I take it is where this $80 million a percentage point came from; and then in the way they do with the antitrust law and a number of other federal legal provisions, triple it.

DR. KESSLER: Mr. Nesbit just whispered in my ear, and let me ask whether people even want to consider it: Some discussion of whether we start from the settlement -- which is guidance to you, and maybe this is not helpful, but maybe it would be -- of whether you start thinking in the range that's currently on the table as we hear it from the settlement discussions in that formula, or whether you start from the Waxman range.

MR. DAYNARD: Can somebody tell us what the Waxman range is, for those who haven't --

DR. KESSLER: I'm sorry?

MR. DAYNARD: Can anyone say what the Waxman range is?

DR. KESSLER: I think you have the --

MS. DuMELLE: You have to understand the language.

It's a noncompliance fee for a manufacturer.

We increased by a dollar for each consecutive violation for each unit of its tobacco product, which is distributed for consumer use.

MR. DAYNARD: So a dollar a pack --

MR. BANZHAF: Or per cigar, or per package of chewing tobacco.

MS. DuMELLE: But it's per manufacturer, as well.

It doesn't hold the industry as a whole; it holds each manufacturer.

MR. DAYNARD: And they get hit if they miss target at all. So it's an on-off thing. It's not --

MS. DuMELLE: They have a baseline in terms of youth preference of tobacco choice, and then they go after that manufacturer, as opposed to the whole industry.

MR. PERTSCHUK: David, in terms of the framing of your question, I think no one is interested in -- my sense is, in considering the 80 cents a pack.

I do think that we might -- the question might be whether we should --

DR. KESSLER: Six cents. The $80 million.

MR. PERTSCHUK: Yes, $80 million, but I do think it would be helpful to get some guidance as to whether we should start with the triple penalties that Dick talked about; up to and perhaps beyond the penalty suggested by Waxman, or that that be the range.

So whether we start at triple the profits or we start at the $1 a pack, something like that.

DR. KESSLER: Julia.

MS. CAROL: I think we should go higher than Waxman, though.

DR. GRAHAM: Just a tactical suggestion as you draft the language.

Whatever data that you choose to use to decide what the ranges are, I think it is very important that the penalty be phrased in terms of a dollar amount or an actual amount.

Profits are a very slippery concept for us to tie this to because that's a net measure; and once there is a tremendous incentive around the economics of profits, people can refigure what their costs and what their revenues are.

So you may, if you feel that you have credibility in some assessment of profit per unit right now from whatever your source, that may be a good data point to base it on; But however you phrase this, I think it ought to be a dollar per unit or ten dollars per unit or what have you, not tied to profits.

Because three years from now, I can see people making very compelling arguments about how their profits are totally different from what we thought they were.

MR. PERTSCHUK: Like Hollywood paying royalties.

MR. SEFFRIN: Yes.

MR. NOVELLI: I think there's a great deal of enthusiasm at the table.

I mean, the enthusiasm is getting people carried away.

Alan Morrison asked a few minutes ago when we started this conversation, what's realistic and what's fair?

The Waxman bill calls for 90 percent reduction over five years or seven years.

Fran has the bill there.

I think that what we ought to do is instruct the group to go back and see what's realistic and fair and use a range of numbers, and not sitting around seeing we can out-do extremist bills and extremist positions.

I go again to a point I made earlier; if we develop something that is pie in the sky, we are going to defeat ourselves.

We are going to play into the hands of the wrong people on Hill and we're going to basically offend the American public. I think realism is important here.

MR. NESBIT: What kind of a process would you propose for determining the range?

MR. NOVELLI: Well, the process that was described by Attorney General Gregoire this morning; and that was predicated on the life of a -- the value of a smoker over his or her life time.

That's one criterion; there may be others.

We heard Dr. Graham say "Let's not use profit; let's use something else." Let's just use something rational.

Let's let the group go back and figure out what is rational, but let's not sit around saying let's see if we can jump six feet over the bar, and raise the bar to nine feet.

MR. NESBIT: Mike, what kind of a group would you put together to determine this?

MR. PERTSCHUK: I'm not sure.

We actually have a -- Alan, will you continue to help us? We have Dick, who has been working on the task force.

I think there are members of the task force who can address themselves to the task.

MR. MORRISON: I feel perfectly comfortable addressing the legal issues and working as a draftsman.

I haven't the slightest idea as to what will work, what the data is, how fast people can stop smoking and what the turnover will be in terms of people moving through the relevant age bracket.

And I do think we need some help on it, which was part of my concern to begin with.

It's not a lack of will or a lack of ability to write some language.

It's really not knowing anything about areas in which we're trying to predict things that we've never had to predict before.

MR. NESBIT: Do we have anyone on the panel who can --?

DR. FIELDING: My suggestion is we separate two issues here.

One is, what are reasonable times to reduce youth smoking certain amounts? And I think that's a totally separate issue from what the penalty should be.

And on the penalty issue, you know, we need an economist or two; and probably industry analysts who really have gone in and frankly know much better than most what the marginal and average cost is of tobacco products of different types that are being sold currently.

MR. PERTSCHUK: Jonathan, it was really you who raised this issue, and I'm wondering whether you'd be willing to take on the task of developing a group of experts on this.

DR. FIELDING: Sure.

MR. PERTSCHUK: And we'll help, but I think we need somebody to take the lead on it.

DR. FIELDING: Okay. Well, I'd be happy to try and do that.

I think we need to separate this issue, which we're talking about, from the performance.

Because also in Congressman Waxman's bill, there are very different performance criteria than in the outline of the possible settlement proposal we were shown this morning.

MR. NESBIT: You're talking about 50 percent after --.

DR. FIELDING: Right, a certain amount of reduction in youth smoking after a period of time.

I think those issues have now gotten joined, and I think inappropriately so.

They're related. We have to think about them separately.

MR. PERTSCHUK: The heart of what committee is really saying is that the criteria adopted for setting that penalty do not seem to the committee to be adequate to serve as a disincentive.

And so it's really the process of looking for what criteria and what numbers; kinds of numbers, range of numbers would begin to serve as serious disincentives to the industry.

MR. NESBIT: In your document, you have performance standards in yours; is that right, on page 15?

MR. PERTSCHUK: We've got a series of criteria, but I think they can --

MR. NESBIT: And Dr. Heyman, you do have --

DR. HEYMAN: Yes, we have them.

On page 7 of my document, drop by 30 percent in five years, 50 percent in seven, 60 percent in ten.

MR. NESBIT: What do folks think about those?

DR. HEYMAN: The penalty would be based on the value of a teen tobacco user to the industry over the lifetime of the individual.

It will be worth approximately $80 million per percentage point by which the target was not met.

MR. DAYNARD: One thing that I think needs to be changed, as we certainly want the first point when the penalty would be assessed to be earlier than five years, because the tobacco companies might very well, in terms of their internal planning, figure that five years from now, different administration, we can pull the plug, different world, different stockholders, what do we care?

So I think we need -- you know, maybe they should be given a two year grace period to do something; but I think after two years we should be starting in there.

I think the curve may be -- well, it may be a little shallow.

In other words, I think we might be able to do a little better than this 15 percent after two years and then sort of add 10 percent a year for a while and see where that leaves us, something along those lines.

I also do think that a strength of this over what I understand just from hearing right now, the Waxman bill to be is I do think some kind of continuous penalty where the penalty is greater the more you miss it, is much better than an on/off thing. The Waxman simply says "If you miss it, it's $1 a pack."

DR. FIELDING: No, it doesn't. No.

MR. DAYNARD: It doesn't. Okay.

DR. FIELDING: It will go up by a dollar for each subsequent time you've not come into compliance.

MR. NESBIT: It's a graduated penalty for --

DR. FIELDING: It's a graduated penalty.

MR. DAYNARD: But I think it makes sense to just have a continuous variable for the same reason I was critical this morning of the notion that you go up to 20 percent and then it cuts off. I think you get odd things in behavior if it turns out that people -- "What the heck, we're going to be stuck with the penalty anyhow."

So I think we want to make it a situation where the more they miss the goal, the more they're punished at each point.

MR. NESBIT: So what do the other panel members about perhaps adding 15 percent -- after two or three years, or perhaps reducing the amount of time, and also introducing the graduated penalty for each target missed?

DR. FIELDING: Do you want to get a consensus, a vote on --?

MR. NESBIT: Yes.

Actually, I guess I would put it to the group, then.

Would be in favor of perhaps taking two years -- use Dick's 2 years, 15 percent; and then go to five years, as Dr. Heyman has it, 5 years, 7 years, 10 years, but also for each target missed, introduce a graduated penalty.

MR. DAYNARD: What I'd like to do is, I'd like to have every year -- there should be an assessment; so these shouldn't be periodic things; it should be on every annual balance sheet after two years.

So in other words, fill in the curve. If it's 15 percent after two years and 30 percent after five years, fill that curve in with a number in each year along the way.

MR. NESBIT: Presumably in an FDA rulemaking, and they would take that into consideration, if they're charged with doing that.

So are people general in support of that, that approach? If you are, raise your hand.

[Show of hands]

MR. NESBIT: Those opposed?

[No response.]

MR. NESBIT: So shall I write down that --

DR. HEYMAN: 15 percent in five years. If you do the math --

VOICE: No; 15 percent in two years.

DR. HEYMAN: Could I perhaps suggest that since the first two years are going to be the toughest, maybe give them 10 percent for the first two years and then make the 15 percent in the next three?

VOICE: Just the opposite.

You're likely to increase dropoff after --

MR. BANZHAF: The initiation of the program, not after it continues for years.

DR. HEYMAN: So good. So 15 percent --

(Laughter)

MR. NESBIT: Then as to how we're going to deal with the penalties, then, Dr. Fielding is going to convene and find a couple of economists and talk to Mr. Waxman's staff.

DR. FIELDING: I'm going to look out on the street,

(Laughter)

MR. NESBIT: I think that we've then dealt with the performance-based standards question.

Are we finished with our first task force, the major --?

DR. KOOP: David wanted to be sure he kept his word to you, Mike, so he wants you to stay right there, Then we'll finish five.

But then maybe we can go home.

MR. PERTSCHUK: I think that the issue that -- there are two issues that have not really been dealt with, and that need input.

I think there was consensus on the range of recommendations that we talked about this morning in the task force, and I don't think they necessarily need discussion; but one area that really does need discussion was the area raised by Jon and by Fran, and reflected in the two pages that were on your desk afterwards; which is adding affirmative acknowledgment of the role of litigation as a tobacco control -- tobacco control policy.

Alan, you may want to talk to that, with what you've suggested.

MR. MORRISON: Well, I don't want to take up people's time.

I hope that people have had time to read the two pieces of paper -- and without asking people to endorse every word of it, I think probably more profitable for them to give their reaction rather than for me to go back and repeat what's been said there.

Everybody should understand, we devised this last night and the committee has not had a chance to look at it -- the task force has not had a chance to look at it in detail.

MR. NESBIT: John.

MR. BANZHAF: I would certainly endorse the concept of the power of

litigation in terms of smoking control; and I think if one looks at the charter per capita consumption of smoking in this country, you'll see that virtually every single dip was directly caused by or certainly happened immediately after some kind of litigation; whether that was getting antismoking messages on the air; whether it was getting the nonsmoker's rights movement; whether it was increased taxes; whether it was the ban on smoking on airplanes; or there was some other kind of litigation, these which occurred were not because of some new scientific discovery, not because of any new major educational campaigns or public awareness campaigns; they came out of litigation.

So that while education and research and public awareness and so on remain powerful tools, I think we've got to admit at this point that it was litigation which is playing at least as significant a role, and certainly was litigation which has been the major force in forming this committee and getting the tobacco industry to agree to make these unprecedented concessions.

It seems to me it's obvious litigation plays an important role here; we should acknowledge it.

MR. PERTSCHUK: There was a specific recommendation which was offered -- Fran?

There's a specific recommendation that was suggested last night which does not now appear in the task force report which was that, in addition to other areas of funding support for the development of the tobacco control movement infrastructure, there will also be recognition of the need for funding for technical support for litigation as an appropriate role for government agencies -- for the fund to be used to support -- Fran, you may want to articulate what it is that you --

MS. DuMELLE: Well, I used the example of an organization like The Advocacy Institute, that was established and secures funds to provide assistance to community-based organizations to be advocates.

Similarly we need to encourage the development of more than one organization that provides the technical assistance and advice, not serving as the public interest litigants such as Alan, but as actually a technical advisory sort of organization -- organizations is what we really need.

So that the range of types of citizen suits can go forward, both at local, state and federal government levels.

MR. BANZHAF: Why would we not want to do the fund those who do the litigation directly? We fund those who do the education, we fund those who do the research; why don't we fund those who sue the bastards?

MS. DuMELLE: No, what I'm saying, John is not that those of you who do litigation in the public interest don't deserve that; but we have far more of you that do the litigation in the public interest than we have in terms of just the technical assistance.

MR. BANZHAF: Well, you'd get a lot more suing if people had the money to do it, and a lot of groups I think would be doing it.

So I would suggest we not restrict it to assistance; if litigation is an effective tool, as I think we're going to admit it is, then presumably funding

to encourage that which may be technical assistance, or may be to bring you the suits themselves.

DR. KESSLER: Let's just review where we are.

The major issues that would be helpful remaining in task force 5. Just summarize.

MR. PERTSCHUK: What I had suggested is that the recommendations of the task force, which are unanimous, did not raise any particular issues for the members; they were consensual.

There were several issues that were left over to be brought to the committee; the first of which was, an affirmative recognition of the role of litigation -- although the task force report discusses litigation, it does not come forward with a recognition that litigation is an important tobacco control tool; so we have language suggesting that.

And secondly, we're now exploring whether there are some specific recommendations in support of litigation that would be appropriate as part of the blueprints.

DR. KESSLER: What type of litigation are you talking about?

MR. PERTSCHUK: Well, in the discussion which Alan has drafted, there are two forms of litigation; one is the support for individual litigation and the other is the support for litigation challenging government enforcement or lack of enforcement of rules.

DR. KESSLER: And under what theory -- past, future?

MR. PERTSCHUK: Future. This is the future enforcement of the --

DR. KESSLER: But on the individual side?

MR. PERTSCHUK: Alan?

MR. MORRISON: Well, on the individual side, it's part of our belief that the process of educating the public and changing attitudes is fostered by litigation, and that that process has not yet been completed.

In addition, of course to the obvious compensation function which still has to go forward, there are these other benefits from individual or class action type litigations.

The second set of litigations are those involving public policy litigation, either in support of the FDA or government agencies when they're trying to do tobacco control things, or trying to force them to do it when they choose not to.

And those are the basic, two different kinds of litigation that have both the direct benefits of the goal in the litigation but also the importance of keeping the issues before the public and informing the public, getting documents out.

And as we point out here, forcing the industry or the agency to actually say why they're not doing something or why they're doing something instead of just simply hiding behind "no comment."

DR. ANDERSON: I have a question about how this actually fits into the report.

You're thinking of inserting this, this four pages into the edit process with a recommendation? Is that --

MIKE PERTSCHUK: Well, it's too long; obviously everything -- but some recognition, as reflected in this report, of the importance of litigation as a tobacco control tool.

That's really what the task force felt was missing in our report, some language to that effect.

DR. ANDERSON: I don't object to that; I was going to state this was too long.

MR. PERTSCHUK: Yes. Everything is too long in our report.

DR. GEORGE ANDERSON: Also, I'm a little bit worried about how you might word the recommendation, particularly since this is part of a blueprint document aimed at Congress.

There's a little bit of a legislative-judicial thing in this, I think that we have to be careful about how you did that if you were to --

MR. PERTSCHUK: The recommendation that we're talking about, or a recommendation, would essentially be added to those -- there's a series of recommendations for the funding of what we've called tobacco control movement infrastructure beginning -- this is on page 13 -- this is the support for state coalitions, along the lines of Assist and others -- and the suggestion for non governmental advocacy organizations.

What has been raised here is the suggestion that it is an additional item that there be support for organizations which provide technical resources for litigation. That would be added to the list of those to be funded, generally.

Yes.

MS. CAROL: Can I just add as well that we just wanted to make it clear in the report that the processes of some of these tools are important as well; not just the outcome.

That from the legal aspect, the outcome of litigation may be important when we win. But in any case, the process of litigating against the industry is a public health education tool.

DR. KOOP: Do you we have consensus that what Mike wants to do is okay?

VOICES: Yes.

DR. KOOP: Nobody disagrees with that?

MR. PERTSCHUK: The only issue before our task force was the issue that Dick

Daynard raised; about whether we should consider setting a cap or defining a cap.

And that actually is the only other issue for Task Force 5.

MR. DAYNARD: Actually in this handout that landed on everybody's plate at some point -- it's probably buried with most of them -- I raised three types of issues; one, whether there should be a cap and if so at what level; and my suggestion was that they're not entitled to a cap but that we might not have any reason to object to a cap as long as -- or might not have very strong reason to object to a cap which was traded off with other things, wonderful things, and some kind of hypothetical settlement so long as that cap actually reflected the maximum amount of money that could be raised; i.e., the revenue maximizing or monopoly price and monopoly profit.

But I certainly don't advocate a cap as to B. But I certainly think that -- the flip side of it, however, I think is very important; which is that there should be no cap below the revenue maximizing -- the monopoly profit.

There should be no cap below the monopoly profit.

So in other words, no cap below what -- if Jeff Harris is right, in 1995, would have been about $32 billion.

That clearly makes sense. It's going to -- may clash a little, with the recommendation that keeps hitting the newspapers of a $4 billion cap. That's the first point.

The second point was how much should the industry pay. That we've dealt with to a large extent in talking about at least a $2 a pack increase in the price of cigarettes.

The third part was on the continuing role of litigation, which goes beyond the points Alan made that we just agreed to in terms of being generally supportive of tobacco litigation and continuing tobacco litigation; but also on details such as for example not absolutely no limitations -- which I think is probably agreed upon by the folks here talking about the negotiations this morning as well.

No limitations on the -- for future litigation based on future misconduct, but also no litigation, no limitation.

My last paragraph, on litigation even based on past conduct.

This goes to questions like class actions; and something that hasn't been much talked about but I understand is part of the industry's wish list that may be -- there may have been some inclination to grant; which is no limitations on case consolidation.

A very esoteric issue, but it mean does the judge have to consider the cases one at a time, or can they do what the judge in Baltimore did with asbestos cases and hear 8,000 of them at one time?

It makes a small difference as to whether the cases are doable or not, as to

whether they're consolidated.

The industry well understands all this stuff, and therefore bars -- and my understanding is the A.G.s are ready to buy this -- bars class actions prospectively, bars consolidations; and then there's a bunch of other talk about new defenses to be thrown in, new hurdles to be put in.

Which is somewhat ironic to accept new hurdles, given this quote I have that most people have probably heard of, from an R.J. Reynolds document that says: the way we win these cases -- to paraphrase General Patton -- is not by spending all of Reynolds' money, but by making that other son of a bitch, to wit: the plaintiff's lawyer, spend all of his.

That's under the existing rules. Now they want to make the rules even harder to make it even more expensive and less likely for plaintiff's lawyers to win.

So I think we ought to come out with a recommendation saying "no way."

MR. MORRISON: As we understand our charge, it's to put together a document of the things that we want, not all the things that we don't want.

And most of what Dick's talking about are things that we don't want or some limits on the things that we don't want.

And our advice is to not start down that road.

MR. DAYNARD: We can put them more positively, though.

MR. MORRISON: I think of any --

DR. KESSLER: As they relate to the public health. As they relate to the public health agenda here.

MR. DAYNARD: In other words, I put it positively. I said that to the extent that continuing litigation is needed, the full range of civil procedures currently available to facilitate this and other litigation must remain available. That's positive.

MR. MORRISON: Well, there's nothing in here now that suggests the opposite. I mean, the underlying notion is that litigation continues to be important for a variety of different reasons, and the less we say that something is unimportant, it seems to me with that goes the necessary predicate that the things we've talked about ought to stay there, and at some point somebody thinks that they shouldn't say that they can come out.

MR. DAYNARD: But people may not understand, Alan. People may say yes, you have your right to sue. That's not to be abridged. Everybody signed on, it's not to be abridged.

But all this other stuff is just procedures and just defenses, and I think it's important that we make the statement that not only do the rights continue but the rights continue along with the normal procedural devices that are available to enforce these rights because without it, you have the appearance but not the substance of rights.

MR. MORRISON: And does the caps fall into that, that Category 2?

MR. PERTSCHUK: There are two separate issues. The first part that you've talked about is exactly what we do believe should be in the report. That is a recognition of the importance of it.

The second was really the discussion of caps, which really is a discussion of a response to a settlement proposal rather than an affirmative response.

So we have no problem with putting in the report the recognition of the importance of litigation, as you've described it, and as Alan has, but thought the discussion of caps awaits for our response to the proposal.

DR. KESSLER: John, and then maybe we can move on.

DR. BANZHAF: I think we have to be realistic. We are writing our won document and it is certainly going to be compared to the settlement which may or may not come out in a couple of weeks.

We've already said we strongly oppose any limitations on the FDA's authority, which is another way of saying we strongly support no limits on the FDA authority.

I think we should do exactly the same thing here.

Dick is saying we should not; we should oppose any limits on the ability of people to get redress, whether that's caps or limits on punitive damages, and so on.

We've got a lot of attorneys general out there who are standing firm on this issue, including many who don't have punitive damages in their own state.

They're standing strong on it, and I think we ought to back them up and adopt this.

MR. MORRISON: I didn't understand Dick's cap point to be what you said, John.

That is to say, do you agree with Dick? Because it sounded to me like you disagree with him to the extent he was talking about there might be some level of caps that might be reasonable.

DR. BANZHAF: Okay. Let me put it positively. I think we should parallel what we did with the FDA. The right of people to collect for damages should not be impinged in any way by limitations on any kind of suit or any kind of damages or any kind of payouts, or any other damn thing. Simple.

MR. PERTSCHUK: Let me read the paragraph --

MR. DAYNARD: You probably put it in a little bit better lawyer --

MR. PERTSCHUK: -- let me read the paragraph that Alan had written, which is:

"The process of litigation is far from running its course. Even if the industry were to fully fund all of the programs anyone can imagine, including

compensating all of its victims, the process should continue until all of the facts are out and the American people truly understand the magnitude of the wrongdoing that is taking place."

And, again, this needs to be summarized.

"The federal government also must be allowed to continue its criminal investigations so that individuals, incorporations, that violated the law, are held accountable as well.

If the evidence shows the kind of outrageous conduct for which the law awards punitive damages, as surely seems to be the case, those claims must not be cut off by legislation fiat.

MR. DAYNARD: Well, that's good on punitive damages, but that doesn't deal with class actions, consolidations, new defenses, caps.

DR. BANZHAF: There are guys who can't stick our head in the sand, say they're not there, we're not going to comment on it, they're going to be there, people are going to ask for it.

MR. DAYNARD: This is clearly the hot issue. That's supposedly why they haven't cut a deal, one of the main reasons they haven't cut a deal.

DR. KOOP: Would you object to the language that Dick has read to us a minute ago?

MR. PERTSCHUK: The language about the importance of litigation and the continuation of litigation, generally.

MR. MORRISON: And the class actions and that part, yes. It's the caps problem.

DR. KOOP: Do we have consensus on the language that Dick just read about litigation?

VOICES: Yes.

DR. KOOP: Okay.

MR. MORRISON: The concept.

DR. KOOP: The concept of litigation.

MR. MORRISON: Dick, essentially what you're saying is, no special rules for tobacco cases.

DR. KOOP: Right.

MR. DAYNARD: Correct.

MR. MORRISON: Is that the concept?

MR. DAYNARD: Right.

MR. MORRISON: That I concept.

DR. FIELDING: Just a point of clarification. Is it my understanding that under what we saw this morning the class action suits would not be able to continue or they would be able to continue?

MR. MORRISON: I wouldn't want to figure it out based on what we were told this morning.

(Laughter)

MR. MORRISON: But I should say to class actions in the smoking context and even consolidations in the smoking context are very different from in the asbestos context or other kind of class actions.

I don't think we should either say now that they are or are not doable. It will not be easy because of the focus on on the individuals. But that's -- it may come a time when the science and the law will change, and so it seems to me we all should keep our hands off of that question entirely.

MR. DAYNARD: There are no special rules handle that very nicely.

MR. MORRISON: All right.

MR. PERTSCHUK: No special rules.

Then the only other request I would make is that there are a series of recommendations made under the international section, including a rather elaborate discussion of an excess profits tax to capture the profits from products sold by American companies abroad that don't conform to U.S. standards.

And it would be useful to get some individual feedback from the Committee members as we proceed on that. It's a rather novel idea.

DR. KOOP: Jeff.

MR. NESBIT: Also, in the event that, again, a settlement comes forward or goes forward to another location, I'd like us to deal with the issue of caps now and try to reach some consensus on that in the event that the settlement or whatever goes forward with that unresolved, so that this group has had a chance to wrest with this somewhat.

MR. MORRISON: When you say "caps" --

MR. NESBIT: I'm talking about caps on punitive damages.

MR. MORRISON: Punitives or actual?

DR. KOOP: You tell us.

MR. MORRISON: There's two different questions.

MR. NESBIT: I think I would start with punitive first.

MR. MORRISON: Well, there is some constitutional law to the effect that, at some point, an industry has been punished enough that there is some constitutional limitation on how much they've punished.

Since this industry has never paid out a penny in actual let alone punitive damages, it seems to me an issue which is way, way down, down the road. That's the first point I would say about punitive damages.

I mean, second is, nobody knows the extent of the wrongdoing of what has gone on, and to measure a penalty of some kind against a course of conduct that we don't know would be irrational, in my judgment, and I think that the issue of punitive damages should simply not be on the table, as far as negotiations is concerned at this point.

DR. KESSLER: Not on the table, meaning?

MR. MORRISON: Meaning that there should be no cap on punitive damages whatsoever.

Certainly, at this time, obviously, any issue could remain open for the future, but there's no rational basis for doing it now.

DR. BANZHAF: Can we vote on that, Mr. Chairman?

MR. NESBIT: Let's have some discussion first.

MR. SEFFRIN: I would like to raise the question, Alan, that goes back to what David Kessler asked, I think, a little while ago, relative to meaningful incentives and penalties.

What about caps on punitive damages established but able to be moved if, indeed, targets are not met, and full punitive damages on future violations of agreements?

MR. MORRISON: Well, again, the theory of punitive damages is some measure of punishment for what's taken place in the past.

It's very hard to set those kind of -- even if one accepted your theory, it's very hard to set those at this point without knowing the true measure of what's taken place.

If what we heard from attorney general this morning is right, there's a lot more to come out as I believe there is, and so I would be very reluctant to try to start down that path, leaving aside any other questions about it in the future.

DR. GRAHAM: It seems to me, again back to tactics and the preparation of this report, we've been asked to prepare a report to lay out a blueprint of sound policy related to tobacco for the use of the Congress.

We get distracted by the possibility of a settlement.

I think we need to prepare the report in the context of why we were asked to do it and without the likelihood of a settlement.

And, in that context, I think we would be foolish to argue that there should be any caps at the present time.

Now, if something happens in the future and a settlement is put before us and before the Congress, we can be asked our advice as to whether or not there is enough other in the settlement to cause us to find some degree of cap on damages acceptable, and we can render out judgment based upon the reality of what is placed before us.

I think we've been asked to lay out a blueprint of sound policy for tobacco and tobacco control, and that we should do so in the context that there will be no settlement.

And with that understanding, I think we'd be foolish to raise or to accept any caps a priori.

DR. HAFNER: I'd like to followup. I think that sets the context of the discussion, because what I heard Dr. Graham also say if there should be a settlement we could consider that in its own context.

The reason I say that, at this moment, is I have this uneasy feeling that in visioning our future potential and wanting that, that in the middle of this if a settlement proposal does come forward, we will measure that settlement proposal against our ultimate goal and say it is so wanting we won't even consider it.

I don't want to pre-pronounce that. In fact, I'll say right now, if that is the intent we might as well send a message to the attorneys general and say we're not going to consider anything anyway.

So I really need to voice that concern about tying these two things together and already deciding based on the conversations today.

MR. NESBIT: Just so that you're clear, there is another scenario here; and that is that there's not a settlement but yet it still goes forward for consideration by this group, by the White House, by Congress, that the attorneys general kick it over to another body. That is another scenario.

DR. GRAHAM: There's not a settlement on this issue?

MR. NESBIT: Right. That's correct.

So then there is not a settlement, and it's other groups then have to wrestle with that.

That's why I'm asking you right now to consider this, because that is also a possibility.

MS. CAROL: Jeff, why don't we just drop the whole on caps?

DR. HAFNER: I'm sorry to interrupt. I have absolutely no problem saying, I don't want any caps. I mean, I'm not struggling with what our vision is of the future. I just have a sense that this vision of our future, if an agreement should come forward, that it will be dead on arrival, unless we're willing to consider it its own context, as Dr. Graham was talking about. That's what I was trying to make clear.

MS. CAROL: Right now, we're not looking at the settlement. We're writing a blueprint for a national plan, and so --

DR. HAFNER: Right. If we are then saying we will not automatically prejudge what comes from any discussion that's written down and sent to us, because our ultimate vision of tobacco goal had already set out the basis on which we were going to say yes or no.

I'd like for them to remain separate, and that's really what I'm asking, is are we going to let them remain separate? Are we going to say it's dead on arrival because, after all, we've already said these things.

I'm for no caps.

MR. MORRISON: If what you're concerned about is that the document not say that we will refuse to consider anything that deviates from what we've proposed here, we have no intention of saying that in this part of the document.

When somebody says it or not, I don't know anything about it, but we surely should be doing what we want, and if somebody makes a proposal, whether it comes from the attorneys general, the President of the United States, the Congress of the United States, we would have to review that in the light of what comes forward.

DR. HAFNER: And I'm just pleading that we understand we have the right to review it when it comes forward. We're not saying that we will not review it unless it makes --

MR. MORRISON: Absolutely.

DR. KOOP: Might I suggest a caveat in the preliminary draft that our staff puts together, stating just that; that this is our position as a blueprint, but we reserve the right to review any settlement that comes from any source in light of that settlement?

MR. PERTSCHUK: And as a blueprint, we oppose caps.

MS. CAROL: Right.

MR. NESBIT: Yes. And litigation is important.

MS. CAROL: We all agree on that?

VOICES: Yes.

MR. PERTSCHUK: Thank you.

DR. KOOP: John.

NICOTINE AND PRODUCT LIABILITY

MR. SEFFRIN: I would welcome any comments. I don't have much to add from what I said earlier this morning.

It would seem to me that the notion and concept of very serious consideration about the universal right to treatment for nicotine addiction and it not be a single event but a lifetime benefit, if you will, is an important issue.

Perhaps what's already been talked about a lot today, I think giving FDA immediate and full authority to regulate nicotine. The others are all important, too.

And I remind you that I mentioned the international piece with some specific examples of things that might be included in that. But I welcome further ideas and critiquing and further ideas about what --

DR. KOOP: Any discussion, John, over II, The Extent of Jurisdiction over Nicotine?

MR. SEFFRIN: Sure.

DR. KOOP: I think that's something we probably ought to seek consensus on.

MR. SEFFRIN: Okay. That starts on page 2. Roman II is on Arabic 2, and the Extent of Jurisdiction Over Nicotine and Other Constituents and Ingredients. I believe the phraseology speaks for itself, but hoping to do it justice, it is very inclusive.

DR. KOOP: The points of this are laid out very well on the next page in bold type, very easily read.

Do we have consensus on that concept?

VOICES: Yes.

DR. KOOP: Anybody in disagreement or raise a question about that?

REV. BROWN: Dr. Koop, were you looking for us to explicitly say that there shouldn't be anything -- regulations, or rules or special deals made to subvert or undercut FDA's regulatory authority?

DR. KOOP: No, no. I just would like to have -- this is all positive stuff, and I just would like to be sure that everybody agrees with it because it's far reaching, and I thought this morning everybody seemed to agree on it, but it would be a sticky point.

Can we assume we have consensus, then, on that issue?

MR. NESBIT: Also, I would assume that it would be consensus, but would everybody around this table agree that beginning the process of regulating nicotine should happen sooner rather than later as opposed to, say, waiting five, ten, fifteen years, sometime?

DR. BANZHAF: Immediately.

VOICES: Immediately.

MR. NESBIT: Begin the process of doing the research now. Okay.

DR. BANZHAF: I'd like to offer just a technical point on Doc No. 4. It says, "Regulate nicotine in a way which is consistent with other nicotine delivery systems."

Since two of them have now been moved to nonprescription drugs, that could be misread to say that cigarettes should be in the same category.

So language, perhaps based upon safety or meeting certain criteria, so it's plain that cigarettes don't automatically get in the preferred category and remain down where the inhaler is now and the suppositories will be one day, God forbid they invent one.

MR. SEFFRIN: Thank you. That's a helpful comment.

DR. HEYMAN: One of the issues that's been raised is whether in fact the intent might be to ban nicotine. It is mentioned in here in reference to that one option is to (unintelligible) for further restrictions a set number of years before Agency can ban nicotine.

Can you comment on that, John, a little bit, in terms of where your Committee was? Because I know that's an issue that has been raised by the industry.

DR. BANZHAF: It has. I might defer to some others to comment on that, but it was walking that line, basically, between what could be argued to appear to allow the Agency to, in a capricious way, ban it prematurely and create a catastrophe for the nation and black markets and all the other kinds of things.

DR. HEYMAN: Sure. One of the things that came up in our Committee discussions that reference advertising was the whole issue that, regardless of what else you say this is the only permissible advertising for an admittedly addictive substance.

So I think those two things just tie together a bit.

MR. SEFFRIN: They do, indeed. Other comments on that? We can use all the help we can get.
Yes.

MS. McGRATH: A comment on one of the bullets on page three, the third bullet, Prohibition on the Use of Marketing Terms, and you've included light, low, and mild. And I know it's a little bit of difference, but would it be important to our organization to add the word "slim"?

MR. SEFFRIN: Thank you.

DR. KOOP: How about "Alive with Pleasure"?

(Laughter)

DR. KOOP: Are there other issues, John, that you would like to be sure you have consensus on? We've got the timing down, we've got the other two down.

MR. SEFFRIN: The disclosure I think is extraordinarily important.

Dick.

MR. DAYNARD: I'm just trying to think on this last suggestion of "slim," that on the suggestion of adding "slim" to light, low and mild, I think "slim" really raises a different sort of issue, really raises the same issues you raise with the "Alive with Pleasure," because they can probably scientifically prove that if you smoke cigarettes you're slimmer on average than if you don't.

So they may have the science there. That's not the point. The point is it shouldn't be permitted for other reasons so maybe we need a different bullet to deal with that.

MR. SEFFRIN: Okay.

REV. BROWN: In which case, you might want to have terms like "natural" included in the list.

DR. KOOP: How about "prohibition of an implied health benefit"?

VOICES: Yes.

MR. SEFFRIN: Thank you. That's good.

Any comments on the six major categories? I felt as though there seemed to be strong support on the statements regarding international even though it falls short of the ideal, and it could be in other categories as well.

Equitable, regulatory, framework. No double standard.

Full information disclosure not only by the industry but privileged documents.

DR. BANZHAF: John, did your Subcommittee have the statement from those 19 people when it worked on this or not?

MR. SEFFRIN: The statement from?
DR. BANZHAF: The 19 health advocates who made 13 specific suggestions. Did you all have that in front of you when --

MR. SEFFRIN: No. No.

DR. BANZHAF: Well, I'd to suggest, then, if I could, now that you have the statement the subcommittee might want to go back; review each of those and either accept it or reject it or whatever else, since they did send it to us.

MR. SEFFRIN: Sure.

DR. KOOP: Yes.

DR. HEYMAN: One other concern on the Nicotine section. You state in your second bullet that the FDA should take appropriate steps to protect public health and further regulate nicotine as soon as evidence suggests necessary.

Could you define how you're going to establish the fact that is now necessary? What evidence will that be based on?

I wonder if we could tighten that up a little bit because there's an awful lot of research out there that indicates nicotine is addictive at fairly low levels and increasing evidence now out of the CDC that differential numbers of nicotine receptors, so some people are more susceptible to the effects of nicotine than others.

MR. SEFFRIN: Well, that's true. John Slade tried to be helpful with this, and I think we're still working on that. I appreciate that comment.

Someone mentioned yesterday that the answer is not to get lower nicotine but to get much higher nicotine levels, and they'll smoke fewer cigarettes and they'll be less lethal. So it's a complex issue.

If you can control accessibility and you're going to maintain the dependency for a period of time, it might be most interesting to see what might happen over the ensuing years before we find a way for total control.

DR. HEYMAN: There is also, of course, the issue of the additives that go into the cigarettes, which heighten the release of nicotine --

MR. SEFFRIN: Yes.

DR. HEYMAN: -- based on the heat generated. So it's a fairly complex issue so John should address that.

MR. SEFFRIN: It is.

One of our Committee members, Bill Novelli.

MR. NOVELLI: Under "international" on the second bullet, I'm not sure whether it was discussed this morning or not, but there is the issue in developing guidelines that would be acceptable to the American public that the threat of pushing tobacco-related jobs overseas would be a potential problem in terms of how the public and members of Congress would see it.
The second bullet under "international" has a potential to do that.

The last bullet, if I read it correctly, John, are we saying that this would be unilateral; in other words, we're talking about American companies advertising in foreign countries and putting them at a disadvantage versus other companies that they would compete with.

I wonder whether that would be seen as equitable and fair.

MR. NESBIT: So you're advocating that we either strike or substantially modify?

MR. NOVELLI: I'm saying that we have to think about both those points for both those reasons.

MR. PERTSCHUK: We also wrestled with this issue in the international section of our report and began with a series of provisions which sought to extend the

reach of U.S. standards in a nondiscriminatory way, ways that do not leave American companies, necessarily, at a disadvantage with their international competitors, with some other strategies for penalizing domestic manufacturers.

It's a set of continuum of provisions, increasingly stringent in applying U.S. standards abroad and it was those sections to which we would request a response from the Committee.

I do think that integrating the proposals of the Nicotine Task Force and others, which have international implications with those in our task force is a task for us to take on.

I think there are some that will be consensual and will be reasonable. There are others which begin to move into the area where Congress is likely to say we are not going to penalize our companies aboard.

I just recommend that those be issues we address, including -- and this was really one of the areas that I had raised at the beginning of the discussion this afternoon, that some of these are goals which may be attainable in the I hope not too distant future, and other goals that are attainable practically in the short term and that that also be addressed in the final report.

MR. NESBIT: If I frame, perhaps, the possibilities that we could take a straw poll on.

On the one hand, you've got the theory of your setting guidelines. You're working with who, you're working with other bodies. You're trying to do as much as you can without actually telling the companies you cannot advertise. You're a transnational company and you cannot advertise overseas. So that's one avenue.

Then there's the other which is embodied in your recommendation, which is the last one, no advertising by transnationals and other countries, and meeting with techniques that are not allowed in the home country.

In other words, you cannot do overseas what we're telling you you can't do here.

So those are the two choices, I think, that you should -- if I were to frame Bill's question.

MR. NOVELLI: I'm not totally sure, Jeff, I understood what you just said. But there's a third point, I think, which is the issue of U.S. jobs being at stake.

MR. NESBIT: Basically, what I'm saying is, the way it stands in the document right now, we're saying, if you're a transnational company and we're going to tell you you can't do something here, you also cannot do it overseas.

That's one possibility.

DR. KOOP: We can't tell people that.

MR. NESBIT: That's the issue. Can we?

DR. HAFNER: I think what these recommendations do is a way of saying we do not intend to have tobacco manufactured in the United States.

If you apply these, I would assume that these business leaders will go elsewhere and import, and I'm not taking a position on this, I'm just saying I really think that's what you're voting on if you vote these kind of recommendations in, is that you want manufacturing of tobacco products somewhere else.

And that may not be bad, but I think that's what you're really voting on with these recommendations.

DR. BANZHAF: I was going to raise another point.

MR. SEFFRIN: John.

MR. NESBIT: Why don't you go first.

MR. DAYNARD: I think looking at the recommendations in the nicotine and product regulation report compared to the much longer set of recommendations in the report of the future of the tobacco industry, it may be sense that it's rather thin if we get rid of bullets 2 and 4, but if you then add the other ones here, or at least many of the other ones, I think the real answer to the question, aside from what our position should be politically here is that what we really want to happen to make a difference internationally is for the United States to use its influence, to really turn around and use its influence internationally to try to apply the standards that we want to see applied here as international standards.

To the extent that we do that in a wholehearted way, we may be able to achieve some of these things and therefore we might be able to feel a little less guilty if we do have to delete the second and fourth bullets.

MR. SEFFRIN: Well said.

DR. BANZHAF: If I can come back and reclaim that time, Mr. Chairman, just for a minute.

I think we can very well do this. My understanding is we do, for example, have standards which prohibit discrimination on the basis of race or sex. They apply to U.S. companies when they operate in countries where this is standard procedure.

We have rules which prohibit bribes and so on in countries where bribes may be standard procedures.

So certainly we can do it, we have done it in other areas.

If I could also make a very small point, John, on another, going on 4.2, which you talked about before, it now says as soon as evidence suggests necessary.

I think a possible reading of that is that the evidence isn't here now, and we need it. Certainly, that's what the tobacco industry always argued. They

argued in the double jeopardy case of Joe Camel.

I think the evidence may very well be that we don't have it. I'd suggest using something like striking out "as soon" and put to the full extent that evidence suggests necessary, so somebody doesn't read this as saying that we believe the evidence isn't there to act.

MR. SEFFRIN: Thank you. That's helpful.

DR. KOOP: Bill.

MR. NOVELLI: I would only add one other point, which is the point that Mike made earlier about the need to rationalize the international aspects from two different, and maybe three different, task forces.

Perhaps the wisest thing for one task force to be charged with that.

DR. HOUSTON: Just one very quick point that John Slade made with me the other day, is pointing out that, so far all we've been talking about applies to American transnational companies.

What if, for example, Japan tobacco starts to look at America as a great export market in the face of all the nasty things that Philip Morris now has to comply with and Japan tobacco doesn't.

So we need to, in some fashion, bring that into account. I'm not sure how you do it but it needs to be put into the mix somewhere.

MS. CAROL: Jeff.

MR. NESBIT: Julia.

MS. CAROL: Thank you. First of all, I just have to say I'm in a little bit of shock that we're spending any amount of time worrying about giving Philip Morris and RJ Reynolds an unfair playing field in the worldwide tobacco market.

(Laughter)

Having recovered from the shock of that even being a suggestion, I have to say that the United States ought to do what it can.

We are not the Japan legislature. They'll do what they can.

Historically, we've used our influence in the other direction for years, including our trade reps and members of Congress, et cetera, and I think it is high time that we use whatever influence we have to influence -- if all we did was rein in our cigarette companies, we'd be going real far, and I think the rest of the world would be very grateful, and we could leave it to them to deal with theirs.

MR. PERTSCHUK: I agree that we ought to do everything we can to use our influence, but again, let me go back to the charge, which is, what would a Congress do that didn't have a tobacco lobby?

The one thing that I do think will be of concern to a Congress is the fact of

American workers losing jobs to foreign workers to companies that are going to practice precisely the same kind of marketing aggression.

Japan tobacco and China tobacco and British American and Imperial and Wathman's (ph) and Rensmith (ph) are all capable of every bit as much aggression as our companies.

I think this is a real problem and that --

MS. CAROL: I wasn't addressing the workers' issue, I was addressing the ban on advertising in other countries.

MR. PERTSCHUK: It is a worker issue.

MS. CAROL: But Bill had brought up two points, and I'm only looking at the one, that a ban on advertising by our companies transnationally would somehow give other international companies an unfair advantage because they could advertise, and it is that with which I am taking issue.

MR. PERTSCHUK: But I still think it's the same issue, Julia; that is, that the companies who are under that kind of handicap will separate themselves, export their production, move jobs, and manufacturing jobs from the U.S. --

MS. CAROL: Well, they already have.

MR. PERTSCHUK: Well, then, it won't reach them. Then it won't affect them.

I do think it's real. I think a real Congress, balancing the democratic interests of public health and workers would look at this issue.

MS. CAROL: Well, then, they can look at it. This is a public health blueprint, you know, for what would be best for public health.

I just think it's high time we do something, we use all of our influence to try to eliminate the scourge of American cigarette companies on the rest of the world.

MR. PERTSCHUK: Influence, yes.

MR. NESBIT: And that was the question that I was trying to frame. Influence, yes.

Should it be maximum influence or should it be, as it's stated in the document now, no advertising by transnationals and other countries, that were -- you know, if we could, we would mandate it.

Should we try to exert maximum influence, set a blueprint, or should it be we want Congress to impose a ban on advertising by transnational companies overseas?

Which is your choice? Use this bullet as indicative of those two choices.

DR. HAFNER: Julie, my concern -- I don't have a concern for the tobacco companies. I really don't, in this case. I have a concern for our own credibility. To say this without just saying we'd just as soon have the

tobacco industry go offshore somewhere and import, I think would show us as being fairly naive.

I think we need to be just a little more forthright in what we're saying, and that is, go elsewhere and produce your tobacco because you're not going to live up to the standards that we want you to live up to.

That's my concern, is that we just seem naive if we leave it in this way.

MS. CAROL: Well, let's take a vote.

MR. NESBIT: Anyone else want to comment before we take a vote?

VOICE: Take a vote.

DR. FIELDING: I guess I share the concerns that Dudley and Mike have raised. I think maximum influence is not necessarily maximum effect.

We could have a maximum effect and drive them off. I think that's very clear. That's what would happen if we kept in bullets two and four, we'd drive them off; they'll set up subsidies elsewhere, whatever we can say, we did our part.

Maximum influence might be if we said we're going to try and phase in standards over time, push the WHO at the same time, try and get them to work with us to do that, so that they were at an unfair advantage.

We might have a lot more influence over the world market than simply taking these actions, so I want to have maximum influence, but I'm not sure what's being suggested to achieve it.

MR. NESBIT: Can I suggest a straw vote? But I would add a caveat that -- I'm not sure who suggested it, but I would like one committee to deal with this and to make it uniform throughout. Would you --

MR. PERTSCHUK: We've got more ink on it, so we will.
MR. NESBIT: With that caveat, the straw poll vote is actually on your section.

How many would like to see both 2 and 4 removed or substantially changed?

(Show of hands.) Those who would like to leave it in as is?

(Several hands.)

DR. KOOP: Thank you. We have consensus of that issue, then. Thank you very much, John.

DR. KESSLER: Why don't we move on to ETS.

ENVIRONMENTAL TOBACCO SMOKE

MS. CAROL: Hubert Humphrey got to speak when you're hungry, and I get to speak when you're tired. However, that may be to my advantage.

Basically, the Task Force on Environmental Tobacco Smoke took the charge of creating an ideal world, which word was used by Drs. Koop and Kessler, and took the position of zero tolerance for secondhand smoke in public places, including outdoor public environments. And that's basically what this report says.

Included in it are some of the justifications, the health justifications, and then lists of some possible specific policy implementations which would achieve that goal.

REV. BROWN: Let just try a tricky one right of the bat.

Is inside people's cars considered a public place?

MS. CAROL: No.

REV. BROWN: Okay.

MS. CAROL: We did discuss that issue and we did not reach agreement.

DR. KESSLER: Let's talk about that. Let's use that as a model for who else wants to throw out location, and then we can discuss it to make a point?

Bill.

MR. NOVELLI: Could you summarize what the Committee has said about smoking in outdoor venues?

MS. CAROL: Yes. We basically outlined, we listed some types of outdoor venues where we thought that secondhand smoke should be prohibited, smoking should be prohibited in order to protect the public, and it's in here somewhere.

Stadiums, I know, were one of them.

I don't know where it is.
DR. BANZHAF: Parks, beaches.

MS. CAROL: Parks.

DR. BANZHAF: Parks and beaches were two other examples.

FRAN: The criteria was places of assembly or congregation for individuals. In addition to public places, we added the criteria where there was assembly or congregation.

DR. KESSLER: So a beach where there's no one else?

FRAN: John, help me out.

DR. BANZHAF: Well, all of these are based on things which already exist. We're talking about banning smoking on public beaches.

Nobody cares if you go five miles away and smoke, take off your clothes, do whatever you want to do.

There are bans on smoking --

DR. KESSLER: Keep just to --

(Laughter)

DR. BANZHAF: All right. Beaches, parks, around the entrances to buildings. There are existing ones in different locations already.

MS. CAROL: Public parking lots that are the levelled lots. I know Berkeley's ordinance does that.

Now, again, this was with the mind that what we were looking at was a far-reaching visionary, what the idea public health -- both ideal and, by the way, we believe to be reasonable, although maybe not reasonably obtained in the next six months.

DR. KESSLER: Did we use the word "idea"? We used the word long term.

MS. CAROL: You used the -- Dr. Koop used the word "ideal" this morning.

DR. KOOP: Did I?

MS. CAROL: Yes, it's in the transcript.

DR. KOOP: I'm not opposed to it.

MR. NOVELLI: What deal?

(Laughter)

MS. CAROL: No, Bill, you said "a deal." He said "ideal."

MR. NESBIT: Now, now.

DR. WASSERMAN: Julia, were there any comments made with regard to protection within the family setting for children from environmental tobacco smoke or did the --

MS. CAROL: You mean in private, in homes?

DR. WASSERMAN: Just the notion of families' responsibilities to children.

MS. CAROL: We dealt with policy. We all agree that parents should not smoke in front of children. We did not have any policy recommendations about what to do about it when they do.

We do recognize that courts have taken action and should continue to do so when they deem it appropriate as a part of other child services, you know, types of rulings.

We did not reach consensus on policy regarding smoking in the home or in private automobiles when children are present.

DR. KESSLER: Why don't we just go around.

Dick.

MR. DAYNARD: Just a format point. I think it's probably worth saying, at least on the home point, what you just said, which is that, you know, I think almost a transcription of what you just said, it's not a good thing for parents to be smoking in front of kids; we're not doing that as a matter of policy, but to the extent that court is taken into account and custody determinations, other types of determinations, and so forth, we're certainly supportive of that process, rather than simply leaving it out, which would suggest that we don't think that that's an appropriate piece, a part of a comprehensive program.

MS. CAROL: I can tell you why we didn't put that in there. It was suggested that we do that, but those members of the Committee who had actually wanted it as a policy thought that to put it, to mention it, and not to recommend it as legislative -- and I'm not one of those people, but I'm trying to advocate their position -- that to mention it and not to go all the way, they would rather have not mentioned it then to mention it and take what they regarded as a weak position on the issue.

DR. BANZHAF: Let me tell you what I actually did propose. This is almost verbatim.

I proposed that children should be protected from exposure to ETS. The same extent that they are under current law as regarding exposure to other dangerous chemicals and unnecessary hazards.

Since almost half the members of the Committee were opposed to that, I was very surprised to find on a Committee concerned with ETS that position.

It seemed to me that rather than have it become public and have our Committee vote against that or be split, I withdrew.

If there is strong support for it, since I've been working for it for many years, I'd certainly like to see it.

We similarly proposed that there be a ban on smoking in automobiles when children were present. Once again, almost half the Committee felt that was too radical an idea.

MS. CAROL: Well, actually, I think all of the Committee liked the idea. We just didn't want it in this report.

Jesse.

REV. BROWN: Well, the question that's on the table, at least, how can we say this, I'm guessing that a lot of us would like to see some language put in that encourages, for lack of a better term, those goals or articulations that we were talking about, knowing that we necessarily don't want to make it policy, and that it may show up in things like counter-advertising campaigns, education campaigns, to encourage those things.

Now, how we say that, I'm not quite sure.

MS. CAROL: I don't have -- John, do you still object to that or not?

DR. BANZHAF: Well, again, the details I'd like to see the language.

My understanding also is that the Youth Committee finding that we did not deal with this now plans to deal with it. Maybe the better thing to do would be to leave it to them. They may be somewhat more sympathetic, and then we can review it when they come in with it.

MS. CAROL: That's fine with me.

MR. ANDERSON: As another member of this Subcommittee, I would point out that we talked a lot about public awareness, exactly in the context that you're addressing it now.

There was a good deal of argument about exactly what public awareness means in the context of this kind of recommendation.

It's very hard to figure out the precise language to get where you're talking about, but I believe very strongly that we need to do that.

MS. CAROL: Yes, I'd go along -- I wanted language in there on that.

Tom.

DR. HOUSTON: If one assumes that a well-funded public education and counter-advertising campaign is done in some fashion, then this certainly needs to be a part of it.

Educating parents about their responsibilities, the problem inherent with ETS, and kids' health, and so on, almost goes without saying, but it does need to be said.

DR. BANZHAF: Julia, but I think we should not fall into the trap of assuming that the best or most cost-effective or quickest way to deal with these problems is public education.
We didn't do it with regard to seat belt, child restraints, and so on.

And very quickly, Tom, you'll remember, you and I were on the Oprah Winfrey Show based upon the fact that a mother lost custody of her child for smoking around it. We go more public education for all the people who watched Oprah Winfrey that day then literally thousands of campaigns could have done.

So I think, in addition to public awareness, which is important, if we really believe that kids should be protected from tobacco smoke, we ought to say kids ought to be protected from tobacco smoke, not just from those parents who might be understanding enough to decide not to smoke around their kids.

DR. WASSERMAN: Could I just ask, John. You had a statement that you threw out to the Committee.

Could you just flesh that out a little bit, because I didn't know the specific details.

DR. BANZHAF: All right. I had started by advising the Committee that in some 15 states where the issue has been raised, the courts have said it is appropriate for a court in a custody dispute to consider one parent smoking, and in effect to count that against them.

As a result of that, there have been literally hundreds, probably thousands of court orders prohibiting smoking in homes, where there are children involved in divorce, particular when they are sensitive.

In addition, there have been four or five cases where complaints have been filed by outsiders, for example, a physician, and something has been done as it is in the ordinary cases of child abuse, child neglect and reckless endangerment. In a few cases, parents have actually lost custody.

There also was a bill in Pennsylvania four or five years ago, which was supported by every public health organization in Pennsylvania, which would have been smoking in a car whenever a child 16 years and under was in it.

We, today, have far more evidence about the health hazards of cigarette smoke to children and we are talking, literally, at this minute, of not only requiring kids to be belted in, which we already do, but federal legislation which would require them to sit in the back seat.

So we can do that to protect them. I don't see why we can't recommend a ban on smoking while kids are in the car.

But as I say, I didn't get support in the Subcommittee, so rather than drag it out, I dropped it.

MS. CAROL: I don't know who's calling on people here.

DR. KESSLER: I think Dr. Koop.

(Laughter)

DR. KESSLER: He's pointing to me.
Dick.

MR. DAYNARD: Well, if I can suggest, I think -- I wasn't there at the Committee meeting, but I think smoking in cars is actually reasonably un-problematic. I mean, that as far as I can tell that it makes sense for us to oppose it.

This is, as John points out, an increasingly regulated environment, especially with respect to kids' safety. It's a serious safety issue. When you smoke in a car, they're small, the smoke just builds up and up and up.

I would suggest we include that here. If not here, then in the Youth Report.

I think the complication on the parental issue is twofold.

One: I don't think anybody is talking about legislation, saying you cannot smoke in your house, it is illegal to smoke in your house.

We're talking, rather --

MR. ANDERSON: Oh, yes, they are.

MR. DAYNARD: Oh, they are? Okay.

MS. CAROL: That was on the table, too.

MR. DAYNARD: Oh, was it? Okay.

DR. BANZHAF: Not by me.

MS. CAROL: When children are present.

DR. BANZHAF: Not by me. Who brought it up?

MS. CAROL: Didn't you want to legislate that you cannot smoke in front of children in their home?

DR. BANZHAF: If you read it, it says that kids should be protected as they are under existing law from other similar hazards. That's what it said.

I have not proposed such legislation. I know of no one who has proposed such legislation.

DR. KESSLER: Then we need not discuss this.

MS. CAROL: Then we need not discuss it.

DR. KESSLER: Hold on, because I do want to move. It's 10 to 5. We have one more committee, and then we have some very important process to reach closure.

Julia, are things clear?

MS. CAROL: They're clear to me.
DR. KESSLER: They're clear to you.

Are they clear to everyone else?

MR. DAYNARD: Are we clear on the cars? Yes?

FRAN: Yes, we're clear on the cars.

DR. KESSLER: Is there anyone who lacks clarity?

DR. HAFNER: Are you saying that we're going to put a provision in there that bans smoking in cars?

MS. CAROL: No.

DR. KESSLER: No.

MS. CAROL: What we were going to do is add back in, which everyone agreed,

that we oppose -- that we --

DR. HAFNER: Do it as an educational?

MS. CAROL: Yes.

MR. DAYNARD: No, that isn't what I was thinking of.

VOICES: No. MR. DAYNARD: I thought there was -- what I didn't hear any opposition to was no smoking in cars when kids were present.

MS. CAROL: Oh, no. That's not what I was agreeing to.

MR. DAYNARD: If there's opposition to it, I haven't heard it yet.

DR. HAFNER: Well, that's because I didn't think it was being purchased, so I didn't say anything.

DR. KESSLER: It wasn't in this. It wasn't in --

MS. CAROL: It was not in this.

DR. KESSLER: Is anyone proposing to put it in?

MR. DAYNARD: Well, we'll try it again with the Youth Committee.

DR. BANZHAF: Why don't we let the Youth Committee deal with it, and we can move ahead with the others.

MR. DAYNARD: Okay, fine.

DR. KESSLER: What does that mean?

MR. DAYNARD: The Youth Committee will deal with.

MS. CAROL: It means I'm done.

DR. BANZHAF: You'll see it again.

DR. WASSERMAN: It would be helpful to have a straw vote.

DR. KESSLER: I think that is for the Youth Committee.

FRAN: We're missing a lot of members now.

DR. KESSLER: That's all right. We can still do a straw vote.

Cars with kids in it.

REV. BROWN: One question, caveat on that. Are we suggesting -- which we didn't say -- that there is some penalty if somebody is caught?

MS. CAROL: There's always a penalty in legislation if you break it.

DR. KESSLER: Wait, wait. What would somebody like to issue? What are you asking the Youth Committee to propose?

DR. BANZHAF: To consider whether or not there should be restrictions on smoking in cars when kids are present. What kind; should they be criminal, civil, should they be the seat belt kind where you can't ticket them unless you stop for something else?

MR. ANDERSON: That's without a law, John.

DR. KESSLER: Let them look into it.

DR. BANZHAF: Sure.

DR. KESSLER: Do we need a straw vote or just say -- you want a straw vote?

DR. BANZHAF: Straw vote to look into it?

DR. KESSLER: All in favor say aye.

(Chorus of ayes.)

DR. HAFNER: We're working with semantics here. Who could be opposed to looking at it? I thought we were trying to be more direct than that and say who's in favor of a proposal that would prohibit ban and punish if you smoke in a car with someone age 16.

That's the question, regardless of how you shape it up. And that what I think the vote's about.

MR. DAYNARD: That's what the vote is about. It's presumably something similar to seatbelts and sitting in the back, and so forth. That's the proposal.

DR. KESSLER: So would you like to restate the question?

Let Dudley state it just the way he stated it.

DUDLEY HAFNER: Simply, the vote is whether or not you would be in favor of a proposal that would penalize people who are smoking in cars where people under 16 years of age were present. You're either for that proposal or you're not in favor of that proposal.

DR. KESSLER: A straw vote; people in favor?

[Show of hands]

DR. KESSLER: People opposed?

[Show of hands]

DR. KESSLER: The Youth Committee has that?

DR. FIELDING: The Youth Committee has that.

DR. KESSLER: Good. Let's move on to the Current Smokers Committee. We will try to do this in five minutes, if possible.

Are there any issues you need guidance on?

CURRENT SMOKERS

DR. HOUSTON: Mr. Chairman, I think we are reasonably well set.

Our Committee was I think the least controversial of the group, and I welcome suggestions from the committee here at the end of the day.

DR. KESSLER: Does everyone have the Current Smokers report in front of them?

DR. HOUSTON: I do appreciate the work that Dr. Seffrin's committee gave on this particular issue in their 'I', and I certainly will incorporate that into this particular report.

DR. KESSLER: Let's start, then.

DR. BENNETT: I'm not really Dr. Veal; I'm Alvina Day Bennett, sitting in for Dr. Veal, with NMA.

Dr. Veal alluded to this this morning. Her concern that we needed to make specific policy recommendations, or her recommendation that there be specific policy recommendations made about cessation and treatment.

Especially as it relates to youth.

As public health people, we certainly are concerned with prevention; but I think we would be remiss if we've used the term 50 million Americans addicted to smoking and that we don't represent them with policy and speak on their behalf in terms of treatment and cessation.

I don't think we have done that adequately; I don't think -- and I apologize for not having the committee's draft in front of me -- but I don't think that we actually stated policy recommendations.

That would assist those individuals who are currently addicted to nicotine in their cessation; and also I think that Dr. Houston mentioned this morning that there were no recommendations form the subcommittee on the tobacco industry's liability for supporting financially those initiatives and programs for cessation.

I think we would be remiss if we did not.

MR. NESBIT: A key question.

DR. KESSLER: Dr. Houston, do you want comment?

DR. HOUSTON: Only that our committee did indeed talk about youth and cessation; mostly to say that there's no good research-based evidence out there about what helps youth quit, as we understand it today.

It just does not exist. Certainly that is one of the key topics about which

research should be done; and it's an issue that we should take into account.

Inasmuch as is possible, we should make it clear to clinicians that helping youth stop smoking is a key priority for what happens with kids and tobacco.

It's another part of a continuum that starts with basic prevention when you're six years old. But today we don't really know what really works with youth and cessation, and that needs to be elucidated and put into place as soon as we can understand it.

DR. BENNETT: Dr. Houston, I understand that part, but what I'm suggesting is that here we have the opportunity to actually make recommendations for policy, to encourage or actually demand that the tobacco industry bear some legitimate responsibility for those Americans who are currently addicted.

DR. HOUSTON: That's a different question than the question about youth and smoking.

DR. KESSLER: Let's translate your point into a possible recommendation and let's see if we can get a straw vote on it.

DR. BENNETT: We actually did do some policy recommendations. And if I may just read these off?

DR. KESSLER: Sure.

DR. BENNETT: These are not specifically related to youth, but these go to addicted --

DR. KESSLER: Sure. I understand that.

DR. BENNETT: Tobacco manufacturers should be required to contribute to and provide financial support for smoking cessation programs; not only for adult tobacco users, but especially for adolescents who are addicted to nicotine as a result of tobacco use. And this speaks to cigarettes and smokeless tobacco.

As part of the public education program, tobacco manufacturers should be required to discuss and encourage the participation of tobacco users in cessation programs, which provide systematic support of therapeutic methods to assist them in overcoming their addiction to nicotine.

Tobacco manufacturers should be required to support and fund research and implementation of cessation programs that are specifically geared to treatment and addressing the needs of adolescent tobacco users and adult tobacco users.

Assess and determine the need to establish smoking cessation programs for adolescents in schools, recreational organizations, churches and communities such that adolescents who desire to quit will have access to treatment in a variety of settings.

These recommendations were made specifically knowing that in practice, there are probably two important questions that physicians and clinicians can ask.

Patients: Do you smoke, do you want to quit? But in practice, it's rarely

asked. There's rare intervention.

DR. KESSLER: Let's see if we can -- just a minute of discussion on those points.

DR. ANDERSON: Just very quickly; I was a member of this subcommittee and actually helped to write up the outline.

I think part of this has to do with the context; and what Tom reported this morning was very accurate.

We didn't go into funding sources; but some of us were operating under the assumption that this would all be paid for by a settlement or some other mechanism that would be related to tobacco industry payment.

So therefore what she has just stated basically fits very nicely with the previous recommendation.

DR. KESSLER: Any objection to the recommendation as articulated?

All in favor?

[Show of hands]

Everyone's in favor?

Okay. Thank you.

DR. HOUSTON: Mr. Chairman, I just need some clarification, then, because some of the other recommendations of the committee have to do with the dual nature of this committee's work.

That is, this presumes that a settlement will occur and that the industry will have -- that there will be a pot of money somewhere for the industry to contribute to cessation.

DR. KESSLER: I think a blueprint is that the company should bear responsibility for the reimbursement of tobacco cessation programs. I mean, that can be part of a national policy.

DR. HOUSTON: That's fine; but short of that we still have recommendations that deal with other methods of financing smoking cessation. Universal coverage for cessation in traditional forms of insurance and so on, and so on.

I don't know whether they're mutually exclusive or not.

DR. KESSLER: I think as it gets drafted we can deal with that so we don't lose those points that you've just made.

Is that reasonable?

DR. HOUSTON: Please.

REV BROWN: Just a quick addition: it may be that we ought to also specifically call out the poor and the least educated who are some of the

primary targets of the tobacco industry's activities, and probably the least -- where we have been least effective up to date in providing cessation activities.

DR. KESSLER: Okay; we can add that and stress that.

Any other comments on the current smokers?

Thank you, Dr. Houston.

Let me -- if you can just take out a piece of paper so I can give you some dates and see whether we can get agreement on this. Should we just give assignments to those who have left?

(Laughter)

DR. KESSLER: We have committed to do this process, and complete this process by the end of this month.

It would be nice, I think, if we kept to that. I think that's Dr. Koop's and my hope, and I assume that's a desire shared by everyone around the table.

Therefore, in order to meet that, let me make the following suggestions and then we can -- as long as we end up by the 30th we can revise this.

That the task force chairs and their staff revise their documents to reflect today's comments and get that revised document to committee staff by the close of business Friday the 20th.

Is there a committee chair who thinks that's not possible to do?

MR. PERTSCHUK: This committee chair thinks it's possible except for the tasks assigned to Jonathan, which are the penalty issues, which are really quite complex.

DR. KESSLER: Let's hold that for a second, then.

MS. DuMELLE: By close of business Friday.

DR. KESSLER: Right, with the exception of Dr. Fielding's assignment, which we can work out separately.

Agreement to have that on the 20th? Committee staff Ruth, Tim, Jeff -- is it reasonable to -- if we get those in the 20th, by the following Friday to have actually sent out to everyone a full consolidated, harmonized draft by the 27th.

Obviously, Jonathan, it's going to mean that your stuff has to come in before the 27th; and we can go back to your stuff in a second. But is that reasonable, Jeff and Tim?

MR. NESBIT: It is. I just want to make sure -- because I've had a lot of inquiries from other folks who want to have input in this process, and I'd like the freedom to be able to seek additional input while we're working on that draft. Is that okay with everybody?

DR. KESSLER: That will give people the weekend, until the close of business -- close of business on Monday?

DR. GRAHAM: Need a clarification already. Are you saying that the first consolidated draft will be in our hands by close of business Friday the 27th? You said send it out.

DR. KESSLER: I said sent out, and I assume it will be sent out by fax.

MR. PERTSCHUK: Both sent out and received on the 27th.

DR. KESSLER: Sent out and received -- well, yes.

DR. GRAHAM: Just say received.

DR. KESSLER: Yes. You will get it on the 27th.

MR. BANZHAF: So people can work on it prior to 4 p.m., if we can.

DR. KESSLER: Then can we ask for, Mr. Banzhaf, this is not meant in these words: crisp and short comments back to the committee staff by the close of business on the 30th?

MR. PERTSCHUK: Could I amend that? As a task force chair, I found it useful to have the members, at that stage, actually recommend language; what to strike and what to substitute.

So that people take the responsibility not just of saying "I don't like it" but they would do instead.

MS. DuMELLE: Or writing a comment --

AUDIENCE: But that doesn't mean that the staff necessarily has to take those words.

MR. PERTSCHUK: No, no. Those are two separate issues; but I think the form of the comments, insofar as possible should be in the form of specific substitute suggestions, suggestions for edits. Because otherwise it's crazy-making.

DR. FIELDING: Is this going to be a harmonized version that has all the parts together. So we send it back, we send basically one set of comments.

MR. PERTSCHUK: Right.

DR. GRAHAM: It's the first draft of the report.

DR. KESSLER: We get back comments by the close of business on the 30th.

MR. PERTSCHUK: One other question, Mr. Chairman. It would be helpful to the task force chairs, I think, within the next day or so to get a suggestions for a uniform format for each of us to use, because we've all used different formats, from the staff.

DR. KESSLER: Do you want to do that, or do you want to just take it in any

format?

MR. NESBIT: I think we'd prefer to work on it ourselves.

MR. WESTMORELAND: I'd prefer to get any raw material in whatever format.

MR. PERTSCHUK: So you're not requiring us to shrink our report from 70 pages to six. Five?

MR. NESBIT: No, we would never --

MS. DuMELLE: No. We'll shrink it for you.

MR. BANZHAF: The Chairman said concise, Mike; it applies to me, it applies to you.

(Laughter)

DR. KESSLER: That's correct.

MR. PERTSCHUK: Okay.

MS. McGRATH: Mr. Chairman, I'd just like to request that when you're seeking additional groups to view this that you include minority groups for Asians and Native Americans and Hispanics.

DR. KESSLER: This timetable, and then this committee stands ready to reconvene at the call of the chairs. May we leave it at that?

DR. GRAHAM: David, you obviously have some strategy in mind once you get everything back after the 30th. Should we anticipate that the convenience of the chairs for reconvening would be within a week, within a month?

DR. KESSLER: No. I think as Dr. Koop earlier said, that we would -- we're not committing to another meeting in person.

We may do it by conference call, we may use other means, we may use back and forth communications.

Let's see where we are with the drafts of the 30th.

DR. GRAHAM: I would simply express, I think real reservations, given the public purpose to which this document is intended to be put, to reaching final resolution that we can all stand behind it and will stand behind it in front of the Congress, without a face-to-face meeting.

DR. KESSLER: That's one of the reasons why we suggested, asked about dates this month. Dr. Koop is going in for knee surgery and I'm going to Yale --

DR. GRAHAM: To something worse, yes.

DR. KESSLER: And we did commit to staff that we would be a 30 day time frame.

I think we just need to assess, Bob, substantively where we are on the 30th;

where we are with the report.

There are ways that we can all talk.

I think somebody suggested earlier by conference call, if we are in relatively good shape. That's one possibility.

I think we've gotten to know each other, and again if things go well as they seem to be going, perhaps a conference call or several conference calls could suffice.

It is a burden on people coming in to town.

Obviously it would be nice to have -- to solidify, but I think if we can keep that open and see where we are with the draft, that would --

DR. GRAHAM: A timely document with low ownership is not useful.

DR. KESSLER: I would strongly urge that the committee staff -- the chair's reports that come in on the 20th, I don't -- I have heard nothing today -- correct me if I'm wrong -- that suggests that that will be the case.

Is there any committee staff that --?

BILL NOVELLI: I would just like to reinforce what Bob just said. I think it's important for all of us to be mindful of Dr. Koop's situation and your time.

But even so, I think this is such a critical document that it is hard for me to believe that we're going to do this by E-mail and fax and so forth.

And I would only ask that we go beyond keeping it open, and to try to set up a meeting, even if it's a half day, so that we can be face-to-face one last time with the final draft.

DR. KESSLER: I think we're open, but I just don't know where we will be --

MR. NESBIT: Can I just ask:

Does everybody here want -- given your preference would you like to have one more meeting, face-to-face meeting?

VOICES: Yes.

MR. BANZHAF: Even if the staff has to chair it or we elect a chairman pro tempore and we fight among ourselves.

MR. NESBIT: Even if Dr. Kessler is at Yale and Dr. Koop is in the hospital. I can sit here; that's okay.

MR. BANZHAF: Staff can run it. You ran half of it today anyway.

DR. KESSLER: You're all invited.

MR. NESBIT: Then I think --

DR. KESSLER: I think we hear it loud and clear; and we really want to get to a document certainly by the 30th where, during this process, everyone has ownership.

Obviously standing up at the end there may be other things that we want to do.

For example, if we have a document on the 30th or thereabouts that we are proud of and has high ownership, maybe we want to do something as a group that's not just coming together; we may want to do something with that document.

MR. NESBIT: And frankly, to be honest, there are other opportunities potentially for a meeting.

DR. KESSLER: With the documents. I just want to keep it open and just be respectful for everyone's times.

Let's think it through; the point is well taken.

But please, we won't even have that opportunity if we don't meet the deadlines of the 20th, the 27th and he 30th.

We will very much -- we will try to get there with high ownership.

MS. DuMELLE: Could I make a suggestion that when the staff sends out the final document for review that they also be asked for areas of controversy.

If there are major areas of controversy that people send comments back, then I think it would be important; but if there's one area of controversy left after you've harmonized and got comment, then I think that perhaps is a conference call.

So I'd almost like to see a "Here are the outstanding issues remaining" and then people can have a sense of, is that a conference call issue or is that a face-to-face?

And I think it would be very useful for us to know if there are outstanding issues in the staff's opinion; and then I think it would be very easy to make that sense of, "do we really want to go through hoops and ladders for a face-to-face, or is it a conference call?"

DR. KESSLER: Right. Absolutely. And when we say keep it open, that's what we mean.

I just want to make sure that everybody feels -- my sense is, today has gone well. Is that --?

VOICES: Yes.

DR. KESSLER: And I just want to check.

MS. CAROL: Great lunch.

(Laughter)

DR. KESSLER: As of this afternoon; the public health community on the public health issues plus some seems to be coalescing behind some general principles.

Is that a fair sense of where we are?

MS. CAROL: It's reasonable and ideal.

(Laughter)

DR. GRAHAM: Seems to be general.

DR. KESSLER: Seems to be generally. That's where I think we are. Thank you all.

[Applause]

[Whereupon, at 5:13 p.m., the meeting concluded.] DISTRICT OF COLUMBIA, USA (59%);

LOAD-DATE: October 15, 1998